

Policy for HHS OOR Methodologist Effort on External Proposals--

Adopted 1/4/21; Revised 9/6/23

This revision was necessitated to add information and clarifications in light of new NIH Policy on Data Management and Sharing that went into effect on 1/25/23. Other funders are expected to follow suit.

Background

The HHS Office of Research (OOR) offers statistical and data management services in support of external proposals and subsequent awards, including consultation for methodological design, power analysis, and development of analytic and data management and sharing plans (DMSP). This support is available to all HHS faculty, and to a more limited extent it is available to HHS students. This support is intended to be a collaborative effort by the faculty/student and the HHS Research Methodologist. However, given limited resources (i.e., a single FTE), great care must be taken to accurately estimate the time demands based on the nature of the Methodologist's planned tasks.

Services provided by the Methodologist include, but are not limited to:

- Consultation on study design: align aims, methods, & analysis
- Power analysis
- Consultation on statistical analysis for manuscript preparation
- Plan of analysis consultation and/or writing
- Assistance with data management and sharing plan
- Coming onto a grant as the statistician and/or to provide data management support
- Training and support for electronic data storage, and online database and survey development using REDCap (redcap.uncg.edu)
- Writing statistical analysis and results sections for papers
- Assisting with manuscript revisions related to analyses/results

Assistance with proposal planning and writing are services of OOR; there is no charge for these services. This reflects HHS' commitment to support effective grant writing. If the intent is for the Methodologist to devote time and expertise to complete work on the project once funded by an external sponsor, appropriate support must be included in the proposal and accompanying budget for this purpose from the outset. Salary savings for the HHS Research Methodologist generated by grant funding are currently being used to pay for GRA support including in the HHS OOR. It would be ideal if this model could be expanded in the future.

The purpose of this document is: (1) to clarify the priorities that drive decisions regarding how time is allocated by the Methodologist; (2) to provide guidelines for determining how much effort should be allotted for the Methodologist in grant budgets based on the nature of the duties to be performed; and (3) to clarify procedures that should be followed when the Methodologist is written into a grant.

Methodological Design and Statistical Support Role vs Data Management Role

Methodological Design and Statistical Support may include:

- Writing, reviewing, or consulting on the preparation of proposal aims, hypotheses, design, and analytic plan
- Conducting or consulting on power analyses for sample size estimation
- Conducting quantitative analyses associated with the primary research aims
- Writing, reviewing, or consulting on research products arising from the grant dataset

Data Management support may include:

- Consulting on the preparation of and/or reviewing Data Management and Sharing Plans
- Creating or consulting on the initial creation of databases and related materials (e.g., parameters, instructions for use)
- Providing resources and or training to other grant personnel to execute the data management and sharing plan (e.g., best practices/approaches to data monitoring)

In the light of volume, workload and needed specialized skills, we are prioritizing the design and statistical support role. Thus, under no circumstances will the OOR Methodologist be charged with the day-to-day responsibilities of data monitoring, nor will they be named as the team member responsible for maintaining data that has been made publicly available. These are critical activities, and the investigators must build appropriate time/personnel into their budgets to complete these activities. The methodologist can provide training, resources, and consultation on these issues if sufficient time to do so is included in the budget.

Priority Areas for Statistical Support

A key goal of the HHS OOR is to enhance the success of faculty in securing extramural funding. We are charged with facilitating an increase in the number of proposals that are submitted and awarded to HHS faculty. As such, efforts to support faculty in securing extramural funding and successfully completing funded research is our highest priority. Many investigative teams need a team member with strong methodological/statistical skills in order to be competitive for funding. The HHS Methodologist is available to serve in that role. Priorities will be considered in the following order:

Highest priority areas:

- Grant proposal development
 - Within this category, the highest priority is submissions on which the Methodologist was involved in the initial planning phase of the proposal, and the [HHS OOR Timeline for Successful Grant Submission](#) was followed (i.e. – notice of need for assistance from the methodologist 2-3 months prior to submission deadline to Office of Sponsored Programs).
- Support for grant funded projects in which the Methodologist's effort is built into the budget.
 - Within this category, tasks and analyses agreed upon in advance via the checklist (see Appendix A) are the highest priority. Add-ons beyond what was agreed to and beyond testing of a priori aims/hypotheses (e.g., ancillary analyses) would be a lower priority. Note that the Methodologist is prohibited from devoting effort to day-to-day data monitoring, sharing, and deposit to repositories.

Lower priority areas include any tasks, other than grant proposal development, for which the Methodologist's time is not being compensated by a sponsor.

- Once project funding for the Methodologist's effort has ended (including if work continues into a No Cost Extension and salary support is no longer provided), the Methodologist's work shifts to an 'unfunded' status and becomes a lower priority; the project work requested of the Methodologist will follow the listed priority areas.
 - The Methodologist is not leaving the project, but this work is competing with other unfunded categories of statistical support.
 - The Methodologist will continue to work with PIs, but response times to emails and phone calls may be longer.
 - Within this category, revise/resubmits of papers initially submitted during the funded period will remain a high priority.
- Faculty manuscripts, presentations, and consultations arising from projects on which the statistician was not funded
- Student support

Guidelines for Methodologist Effort on Grants

The following guidelines are to be considered and applied when determining the Methodologist's effort on external proposals and awards:

Pre-Award:

- The degree of effort should reflect the Methodologist's duties and involvement with the project.
 - This effort should accurately reflect the scope and complexity of the statistical needs.
 - For multi-year projects, this effort may vary for each funding period.
 - See the "Statistical Effort Allocation Examples" section below for a description of appropriate effort depending on the Methodologist's duties and the level of involvement.
- Statistical support and data management are two separate services; each encompasses a distinct set of responsibilities and should be planned for separately in the project budget.
- To facilitate this planning, the faculty PI should complete the 'HHS OOR Statistical Needs Checklist' to the best of their ability and share it with the Methodologist during an initial planning meeting. This will guide the initial discussion and ensure that the statistical support and data management being requested by the PI is fully understood. It will also provide guidance in determining the Methodologist's effort on the entire project. Please see Appendix A.
- It is recommended that the Methodologist be named as a member of the research team/key personnel and be allocated some portion of the credit for the grant and subsequent distribution of indirect costs that is commensurate with the Methodologist's effort/role on the team.
- It is also recommended that authorship plans be discussed and agreed upon. In general, it is expected that the Methodologist would be included as an author on papers if involved in the planning, execution, and/or write up analyses. This is consistent with authorship recommendations by many professional organizations. Furthermore, this further enhances the

Biosketch of the Methodologist contributing to more positive reviews of subsequent grant proposals.

Post-award:

- If a budget is cut at award or at subsequent re-award, there cannot be a cut in the Methodologist's time or effort without a discussion with and approval from the HHS Associate Dean for Research.
 - If there is a reduction in effort, then there will likely be a corresponding reduction in the Methodologist's responsibilities.
- If grant-related work involving the Methodologist continues into a No Cost Extension, salary support should be provided to the extent possible.

Statistical Effort Allocation Examples:

These are examples of allocation of effort on grants depending on the Methodologist's duties *as a statistician* and the level of involvement with a project.

5% - <10% Effort (~2-3 hrs a week/8-10 hrs a month). This level of effort is appropriate for funding years in which the statistician's responsibilities might include:

- Occasional meetings/consultations with the PI about analytic plans
- Consult on electronic database construction, for example:
 - Variable metadata: names, wording, value labels, missing values, etc.
 - Structure: longitudinal or standalone, event-spacing, etc.
- Attendance of some project meetings as needed
- Supervision of analyses that others (e.g. – graduate students, post-docs, etc.) conduct
 - Discuss decisions regarding recruitment, assignment, or design changes, specifically regarding implications for statistical analyses and interpretation
 - Discussing/finalizing specifics for conducting analysis for manuscripts
 - Review analysis results and discuss any revisions to analysis
 - Troubleshoot specific issues arising when conducting analyses
 - Review analysis and results sections of manuscripts/research products

10% Effort or higher (4 hrs a week/16 hrs a month). This level of effort is appropriate for funding years in which the statistician's responsibilities might include any examples listed above plus or superseded by:

- Development and implementation of routine randomization/matched assignment procedures
- Ongoing consultations with the PI, and attendance of project meetings as necessary

- Supervision of analyses that others (e.g. – graduate students, post-doc’s, etc.) conduct
- Consult on and provide feedback for analysis and results sections for manuscripts, presentations, etc.
- Conduct analysis for a clearly defined model, and provide a summary of results

15% Effort or higher (6 hrs a week/24 hrs a month). This level of effort is appropriate for funding years in which the statistician’s responsibilities might include any examples listed above plus or superseded by:

- Develop and implement more complex randomization/matched assignment procedures
- Generate and run routines (at defined intervals) for recruitment and retention monitoring
- Conduct preliminary analyses (e.g. – examination of distributions, ranges, data quality)
- Conduct analyses outlined in the analysis plan of the grant proposal
- Write analysis and results sections of manuscripts, presentations, etc.

20% Effort or higher (8 hrs a week/32 hrs a month). This level of effort is appropriate for funding years in which the statistician’s responsibilities might include any examples listed above plus or superseded by:

- Regularly attend project meetings
- Conduct complex and/or time-consuming analyses outlined in the analysis plan of the grant proposal
- Coordinate analyses for multi-site studies

Data Management, monitoring, and sharing encompasses a distinct set of responsibilities and should be budgeted for separately from statistical support. This is, in fact, required by NIH and other funding agencies are expected to follow suit. Again, these responsibilities likely wax and wane across each year of the funding period; therefore, budgeted effort for data management is likely to vary by year as well.

5% Effort or higher (2 hrs a week/8 hrs a month). This level of effort is appropriate for funding years in which the data manager’s responsibilities might include some combination of:

- Periodic distributions of surveys from a pre-defined list of participants

- Execution of (granting/restricting) end user privileges within an electronic database
- Periodic (e.g. – monthly, quarterly, etc.) reports of the current state of the dataset
- Provision of data for annual reports to funding agencies

10% Effort or higher (4 hrs a week/16 hrs a month). This level of effort is appropriate for funding years in which the data manager's responsibilities might include any examples listed above plus or superseded by:

- Consultation on construction of electronic database (prior to data collection)
- Troubleshooting or minor modification of an electronic database after data collection has begun
- Construction of smaller or less complex electronic database
- End user training at prespecified times

15% Effort or higher (6 hrs a week/24 hrs a month). This level of effort is appropriate for funding years in which the data manager's responsibilities might include any examples listed above plus or superseded by:

- Construction of large and/or complex electronic databases
- Regular end user training and troubleshooting support
- Significant alterations to an electronic database after data collection has begun

Multi-Year Project Funding Scenarios:

The Methodologist's involvement on multi-year projects may vary over the course of the initial project period and may extend into a No Cost Extension; the effort of the Methodologist should accurately reflect the amount of work that is expected during these time periods.

Please Note: Once the funding period is over or the funding for the Methodologist's effort has ended, the Methodologist's work shifts to an unfunded status, and the project work requested of the Methodologist will follow the **Priority Areas for Statistical Support** outlined above.

The following scenarios may provide some guidance as to what the effort may look like across the project years. Please note that these examples assume the Methodologist is only serving as the statistician (i.e. - is not also serving as the data manager).

5-Year Project Scenario, planning all at beginning, analyses primarily at end:

- Year 1 – 5% Effort
 - Statistician consults with PI and data manager on data collection and management procedures, and variable coding

- Statistician collaborates with PI and data manager to generate reports
- Statistician attends team meetings as necessary
- Year 2 & 3 – 5% Effort
 - Given that active data collection is in full swing, the Statistician is only needed for consultation purposes as statistical support needs are less during these years, and there may be some mid-point analytical requests
 - Statistician collaborates with PI and data manager to generate reports
- Year 4 & 5 – 15% Effort
 - Statistician is actively analyzing data, cleaning data (in collaboration with the data manager), etc. and is involved with papers and dissemination

5-Year Project Scenario, planning/data management for study with multiple cohorts/waves (Time 1 [T1] then Time 2 [T2]), analyses midway for Aim 1 and at the end for Aim 2:

- Year 1 – 10% Effort
 - Statistician consults with PI and data manager on data collection and management procedures, and variable coding for T1
 - Statistician develops and implements randomization procedures for T1
 - Statistician collaborates with PI and data manager to generate reports
 - Statistician attends team meetings
- Year 2 – 5% Effort
 - Given that active data collection is in full swing, the Statistician is only needed for consultation purposes as data management needs are less during these years, and there may be a mid-point analytical request
- Year 3 – 15% Effort
 - Statistician consults with PI and implements randomization procedures for T2
 - Analyses for Aim 1 publications begin; analyzing data, cleaning data (in collaboration with the data manager), etc. and is involved with papers and dissemination
- Year 4 – 15% Effort
 - Statistician is actively analyzing data, cleaning data (in collaboration with the data manager), etc. and is involved with papers and dissemination for Aim 1
- Year 5 – 20% Effort
 - Statistician is actively analyzing data, cleaning data (in collaboration with the data manager), etc. and is involved with papers and dissemination for Aim 1 and Aim 2

3-Year Project Scenario, planning all at beginning, analyses primarily at end:

- Year 1 – 5% Effort
 - Statistician consults with PI and data manager on data collection and management procedures, and variable coding
 - Statistician collaborates with PI and data manager to generate reports
 - Statistician attends team meetings as necessary
- Year 2 – 5% Effort

- Given that active data collection is in full swing, the Statistician is only needed for consultation purposes as statistical support needs are less during this year
- Statistician collaborates with PI and data manager to generate reports
- Statistician collaborates with PI to begin planning primary analyses
- Year 3 – 15% Effort
 - Statistician is actively analyzing data, cleaning data (in collaboration with the data manager), etc. and is involved with papers and dissemination

Best Practices and How We Want Faculty to Work with the Methodologist:

- Be good and timely communicators – this is a collaborative relationship for the Methodologist, the PI, and the project team. Our goal is to provide statistical services and tasks as efficiently as possible in an effort to continually improve the timeliness of support provided to HHS researchers. The Methodologist is frequently asked for rapid turnaround with little advance warning. This makes it difficult to manage workload at any given time particularly given the Methodologist is concurrently working on a high number of grant proposals and funded projects with multiple teams from a variety of funders. Investigators should reach out in advance to alert the Methodologist to needs and be open to negotiating timelines for analyses and related tasks that take into account the Methodologist's multiple ongoing projects. In general, the Methodologist will prioritize requests as follows: 1) grant deadlines; 2) annual report to funder deadlines; 3) revise/resubmit deadlines; all else being equal, projects which gave advance notice will be prioritized.
- Be advance planners – strategically think about the entire project and all the steps involved with it; plan the statistical needs timeline accordingly. The checklist in Appendix A is intended to facilitate detailed discussions about analytic/data management needs prior to grant submission. It is suggested that needs be re-assessed/timelines adjusted and shared with the Methodologist at the time of award and annually thereafter. Reviewing at the time of annual reports to funders are due is suggested as one way to approach this.
- Please be aware that the Methodologist has a 12-month appointment and as such is available all year including the summer months and earns vacation days that may be taken throughout the academic year or summer. To every extent possible, the Methodologist will provide advance notice of leave time to PIs of funded projects on which the Methodologist is supported.

Appendix A: HHS OOR Statistical Needs Checklist

Phase/Task	NA	Responsible party				
		PI	GA	STF	OOB Method	OOB GA
Grant Preparation/Revision(re)						
(re) Align aims, methods, and analysis						
Develop or consult on analytic plan						
Provide effect sizes for power estimation ¹						
(re) Conduct power estimation						
(re) Respond to analytic critiques						
Analyze/summarize data for preliminary studies section						
Write Data Sharing and Management Plan						
Data safety and monitoring plan as it relates to electronic database platform, data security and quality (CT only) ²						
Just in Time						
Modify/Supplement data management plan as needed						
Prior to Data Collection						
Prepare and implement detailed plan for constructing the electronic database (naming conventions, entry shells/templates, entry directions, reliability checks, validation, scoring routines)						
Train staff on data management/monitoring ³						
Reliability checks/validation						
Gather scoring materials						
Create/modify syntax for scoring, reliability						
Determine survey distribution rules/procedures						
During Data Collection						
Data entry						
Regular checks of data entry quality						
Consult on data entry issues that arise						
Troubleshoot/Modify electronic database						
Provide descriptive data for reports to funding agency						
Generate mid-project datasets to be shared by request						
Preliminary Analysis (may occur during data collection)						
Descriptive statistics/examine distributions/transform variables						
Calculate reliability or other indices						
Assess constructs or create scores to reduce data dimensionality (e.g. – EFA/CFA, PCA, etc.)						
Summarize select data for annual reports to funder						
Primary Analyses (Hypothesis testing)						
Analyses listed in proposed aims						
Consultation on analyses beyond primary aims ⁴						
Manuscript Preparation						
Write analysis & results section						
Create results tables and figures						
Respond to analysis critiques for revisions						

Note: Black filled boxes indicate tasks **not** performed by the HHS OOR Methodologist/GA. Boxes with gray fill indicate tasks not typically included in statistician effort and would require separate discussion/effort.

¹ Effect Size expectations often depend on the field of study and the proposed research design. It is the responsibility of the PI to provide effect size estimates, or to make the decision to use conventional values for “small,” “moderate,” or “large” effects.

² CT = clinical trial

³ Staff training should be a collaborative effort between PIs, CoIs, the data manager, and the statistician. Staff oversight is the responsibility of the PI or designated party (e.g., co-I, Project Coordinator)

⁴ Availability to support analyses beyond the primary aims must be discussed and agreed upon prior to requests. This may also occur prior to the completion of data collection particularly in longitudinal or multiple cohort designs.