Duke University School of Nursing

Center for Nursing Research

Research Design and Statistics Core

General Guidelines on Statistical Collaboration/Consultation

(Oct 1, 2017)

Overview

The Research Design and Statistics Core assists researchers with all sizes and types of research projects. Specific services include:

- **Pre-award grant applications**, including think tank, study design, sample size calculation, and statistical analysis plan.
- **Funded projects**, including NIH, foundations, and other funding agencies.
- **Expired funded projects within a grace period**
- **Small grants,** including DUSON pilot or Duke internal grants
- **Unfunded projects**, including data analysis, interpretation, and manuscript preparation for supporting future grant application.

The aim of this general guidelines is to foster an effective partnership between principal investigators (PI's) and statistician /statistical investigator / co-investigator (hereafter denoted as SI's) for ensuring the quality of data, the rigor of statistical analyses, the appropriateness of interpretation of results, and the completion of the project in a timely manner. The following sections address the responsibilities of a SI, the responsibilities of a PI from a SI's point of view, and a brief summary of the ethical principles that guide statistical collaboration/consultation.

A. Responsibilities of an SI on a research project (see Table 1):

Table 1. Responsibility and Roles for Research Design and Statistics Core members

Type	Team approach		Individual approach
	Faculty Statistician	Statistician III	Ph.D. prepared Statistician
Pre-award	• Think tank • Mock review • Draft research design and analysis method session	• Not required	• Think tank • Mock review • Draft research design and analysis method
Funded projects or small grant	• Work with PI to create long term and short-term timeline for the project • Supervise statistician III to meet deadlines. • Finalizing analysis plan and report • Provide suggestion for more advanced statistical methods	• Draft analysis plan with help from faculty statistician • Conduct analysis • Draft report	• Work independently based on allocated effort percentage on the project
Expired funded project (within grace period)	• Discuss dissemination plan and timeline with PI • Provide suggestion for more advanced statistical model and methods • Finalize method and result session for manuscript	• Conduct analysis • Draft method and result session for manuscript	• Work independently based on allocated effort percentage on the project

I. For pre-award grant applications

1. A submission of a Statistical Support Request Form from a PI is expected **8-12 weeks** prior to grant application deadline. A design/methods think tank meeting with an SI may be initiated by the PI before or after the submission of the statistical support request form.

2. The SI will work closely with the PI on completing study design, data analysis plan, and power and sample size calculations **6-8 weeks** prior to the grant application deadline.
   a. It is important and typically most effective to involve the SI in designing the study from the beginning to ensure that the study design, sample size, etc. are adequate to meet the specific aims of the project.
   b. Further, the SI can assist with and/or provide randomization or blinding procedures, intervention strategies, timing of procedures and visits as well as other study design issues related to data collection.

3. The SI will work closely with the PI on final edits for the grant proposal **4-6 weeks** before the grant application deadline.

II. For funded projects/ expired grants within a grace period/ small grants:
1. We may adopt a team approach or an individual approach based on the PI's preference and the availability of the stat core members. The team approach includes a Ph.D. prepared statistician as a Co-Investigator and masters prepared statistician as a statistician/analyst. The individual approach includes only one primary statistician who will take complete responsibility. The detailed responsibilities are described in Table 1 based on type of projects.
2. The scope of work and timeline should comply with the statistical analysis plan on the original proposal that was approved by the funding agency. In addition, it is not uncommon to have deviations from the original statistical analysis plan. In these instances, the SI and the PI must discuss the deviations from the original statistical analysis plan as well as any secondary analysis the SI deems necessary to perform in conjunction with the main analysis. Additionally, the revised final scope of work and timeline need to be agreed upon between the PI and the SI.

III. For unfunded projects:

1. A submission of a Statistical Support Request Form from a PI is expected with a reasonable lead-time for completing the project, usually **2 to 4 weeks**.

2. The SI's level of involvement and timeline on an unfunded project should be discussed and an agreement reached between the PI and the SI at the start of the collaboration. PI's may request up to 10 hours of consultation time per semester on an unfunded project.

B. Responsibilities of a PI from an SI's point of view

1. Collaboration between the PI and SI is most effective if good communication practices are established. The PI is responsible for ensuring that the SI has a clear understanding of the objectives of the project by providing sufficient, relevant information. It is not uncommon for the SI to be unfamiliar with the terminology and key components related to the PI's content area of research. PI's should provide the SI sufficient time to become comfortable with the content and nature of the data to be analyzed.

2. The PI is responsible for providing a complete and accurate description of the data collection procedures, eligibility criteria, issues during data collections, and protocol deviations.

3. Any publications or reports produced as a result of the project should acknowledge the contribution made by the SI, consistent with the level of involvement. It is also appropriate to include the SI as a co-author on manuscripts on which the SI puts forth significant effort, including writing the statistical methods section, providing statistical results, or reviewing the manuscript for correctness.

C. Financial consideration (see Table 2)

Table 2. Suggested efforts allocation for Research projects

	Suggested effort allocations			Grace period after grant end date*
	Team approach		**Individual approach**	
	Ph.D. Statistician (Co-I)	Master Statistician (Analyst)	Ph.D. statistician (Co-I /statistician)	
Pre-award	Covered by CNR general research time	NA	Covered by CNR general research time	NA
NIH R01 equivalent+	Year 1-2: 5% Year 3-5: 5-10%	Year 1-2: 5-10% Year 3-5: 15-30%	NA	Up to 8 months
NIH R21 equivalent+	Year 1-2: 5%	Year 1: 5% Year 2: 10-20%	Year 1: 5-10% Year 2: 10-20%	Up to 8 months
Foundation grant (25-100k in funding)	NA	NA	5-10%	Up to 5 months
Duke internal grant /small external grant (<25k in funding)	Covered by CNR general research time	Covered by CNR general research time# (5-15% efforts)	Covered by CNR general research time# (5-15% efforts)	Up to 2 months
DUSON pilot grant	Covered by CNR general research time	Covered by CNR general research time# (5-15% efforts)	Covered by CNR general research time# (5-15% efforts)	None
	Faculty without funding should use **Stat lab** for general statistical support			
	If additional support needed, they can submit a request for up to 10 hours of support per semester			

Notes:

* Grant end date will be determined by either funding deadline or official no-cost extension date. Grace period request will be reviewed by the CNR leadership and a decision for level of support will be made case by case.

+ Effort allocation variation depends on budget allowance and scope of work in the grant. If it falls below the lower limit, please discuss with the Co-I (statistician).

1. The Research Design and Statistics Core is supported partly by funding from the Center for Nursing Research in Duke School of Nursing. This funding allows us to provide some services without charge. Pre-award grant applications and analysis of preliminary data in support of grant applications receive highest priority for unfunded efforts.

2. Effort allocation guidelines for funded/small/expired funded research: In general, funding for SIs should not fall below 10% of total effort per SI per year on a single project. Intervals with funded effort falling below 10% require approval by the Associate Dean for Research and the Core Director. Table 2 provides a summary of the different types of projects.
   a. Funding should be matched to the size, scope, and complexity of the data analysis and study design. Key determinants include the number of primary and derived study variables that will be collected and analyzed, the quality and completeness of the data to be supplied for analysis, and the complexity of the programming necessary to assemble input data and implement descriptive and analytical statistical methods.
   b. 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 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).
   c. There are some grant mechanisms that do not support funded effort by an SI; this may include some K awards and DUSON pilot and small internal grant from Duke. In this case, the PI should discuss the proposal with the Associate Dean for Research and the Core Director.
   d. Any changes in percent support made during proposal writing or after research has been funded must be made jointly between the PI and the SI. If the SI's percent of efforts are reduced due to budget cuts, this will also require consultation between the PI and the SI.

D. Ethics in statistical collaboration/consultation

1. Both SI's and PI's should be guided by professional and scientific ethics, which promotes the integrity of the data analysis and conclusions. The SI, together with the PI, has the responsibility to ensure data quality, conduct rigorous analysis, and appropriately interpret results.

2. S'Is are to use methodology and data without prejudice or favoritism that are relevant and appropriate to produce valid results.

3. All SI's are to be held accountable to the ethical guidelines from the American Statistical Association (http://www.amstat.org/asa/files/pdfs/EthicalGuidelines.pdf).