Duke University School of Nursing

Center for Nursing Research

Research Design and Statistics Core

General Guidelines on Statistical Collaboration/Consultation

(September 20, 2016)

Overview

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

- **Funded projects**, including NIH, foundations, and other funding agencies.
- **Pre-award grant applications**, including study design, sample size calculation, and statistical analysis plan.
- **Unfunded projects**, including data analysis, interpretation, and manuscript preparation for future grant application.

The aim of this general guidelines is to foster an effective partnership between principal investigators (PIs) and statistician / statistical investigator / co-investigator (hereafter denoted as SIs) 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:

I. For funded projects:

1. The scope of work and timeline should comply with the statistical analysis plan on the original proposal that was approved by the funding agency. It is also not uncommon that there will be 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 conducted 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.

2. The SI is responsible for spending enough effort on data preparation. A clean, suitably-structured, and well-documented data set is critical for efficient and accurate statistical analysis. While it is not required, using the Research Electronic Data Capture (REDCap) can greatly simplify data collection and minimize costly and time-consuming data clean-up activities. Regardless of the software used to record

data, a quality data preparation will facilitate an efficient transition from raw data to data analysis.

II. 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.
   c. The SI will highlight to the PI any known or suspected limitations in the data that may compromise the validity of the project.

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

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 agreed between the PI and the SI at the start of the collaboration. Other factor to be considered include the project's status, the nature of the request, and the SI's workload.

3. Regardless of the scope of work agreed upon, there will be certain activities and responsibilities that the SI needs to take on as a standard practice. In case that the PI is not aware of issues that may reduce the rigor of the study, the SI has responsibilities to use expertise to make and inform the PI appropriate adjustments.

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. The PI may ask for feedback to gauge the SI's understanding of the project's scope. 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. PIs 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. Missing data and protocol deviations could potentially impact the validity of the study's conclusions. Often an SI can suggest valid approaches for proceeding with analysis despite these issues to ensure the rigor of the study and its conclusions.

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

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. Statistical support on other unfunded projects will be based on the availability of resources.

2. Effort allocation guidelines for funded research:
    a. 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.
    b. 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.
    c. 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).

d. There are some grant mechanisms that do not support funded effort by an SI; this may include some K awards. In this case, the PI should discuss the proposal with the Associate Dean for Research and the Core Director.
e. 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 efforts are reduced due to budget cuts, it also requires consultation between the PI and the SI.

D. Ethics in statistical collaboration/consultation

1. Both SIs and PIs 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. SIs are to use methodology and data without prejudice or favoritism that are relevant and appropriate to produce valid results.

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