

Introduction to Collaborative Grant Writing for Biostatisticians

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Introduction

- Grant writing is a major activity you will engage in as a biostatistician.
- This is especially true for PhD trained biostatisticians.

- In this talk we will focus on:
 1. The components of the science of the grant.
 2. The administrative components.
 3. What you should expect from the PI of the grant.
 4. What the PI should expect from you.

- In this talk we will not focus on:
 1. The technical aspects of particular designs, analyses or sample size calculations.

Language of Grants

- **PI:** Principle investigator – the researcher responsible for the overall scientific direction of the award.
- **MPI:** Multiple PI's – there is one or more individuals responsible for the overall scientific direction of the award. Later in your collaborative career this may be you (you could also be a PI!) if the grant ties methodology together with science.
- **Key Personnel:** Individuals that have a substantive role in the award and cannot be easily replaced by another. For most grants you should be a key personnel; although there will be exceptions.
- **Biosketch:** A special version of your CV that highlights your expertise and specific role on this award.
- **Budget justification:** Paragraphs explaining your role on the grant.
- **Biostatistics Budget:** The dollar amount on the award budgeted for you and others on your team needed to conduct the work.

Language of Grants

- The institute: The NIH is comprised of 27 institutes (I think). The grant will be being framed for one of these institutes.
- The study section: The group of reviews that will evaluate the science of the award. Over time you will become familiar different study sections and the things they look for. They each have their own flavor.

Types of NIH Grants

- Career (K) awards – career development award. Covers 75% of the PI's time.
- Independent investigator awards (R-type grants):
 - R01 award: A 3-5 year award focused on a self contained set of research ideas.
 - R21 award: A 2 year award (\$275K total) focused on the developmental aspects of the research. Could be high risk but high reward.
 - R03 award: A 2 year award (\$100K total) focused on a pilot study/aspect of a project.
- U/P award: A large team science award tied around a scientific theme. Often the equivalent of 3+ R01 awards with cores to support the research. Most have a data and statistics core as part of the application.

Grant Sections (R01)

■ **Grant Sections (13 pages total):**

- Specific Aims (1 page only)
- Research Strategy (12 pages)
 - a. Significance
 - b. Innovation
 - c. Approach
 - Preliminary Studies for New Applications
 - Progress Report for Renewal/Revision Applications
 - Details of Research Design and Methods
 - Limitations and Alternative Strategies
 - Timeline

Specific Aims

- Lays out the scope of the research project
 - why it's important and new, what will be learned, how it will be done and what will come after.
- Each of the other sections addresses one or more of these points in greater detail
- It is of particular importance to help write (see) the aims and hypotheses so that you can
 - Translate the scientific hypotheses to testable statistical hypotheses
 - Understand the context of the questions and hypotheses when you have to make choices about design and analysis strategies

Approach: Preliminary Data

- The preliminary data
 - are those that support some aspect of the grant application – e.g.
 - Ability to collect the data
 - The measures chosen are better than other measures
 - Small sample results consistent with expected direction of association
 - may be organized according to specific aim, or all at beginning of Approach
 - are important to have in order to conduct power analyses, but often help refine hypotheses and analysis strategies

Approach: R& D

- The research design and methods section
 - is the place where the details of the proposed study are described.
 - organized according to specific aim – there are exceptions to this, but in general, this is common approach since it helps the reviewer.
 - needs to have enough detail so that the reviewers can evaluate the approach and believe that you know what you're talking about, but not so much that the reviewer gets bogged down in details that distract from the main message (or gets irritated that you couldn't be concise).

Outline of the Approach (after prelim data)

Some or all of the following may be repeated for each specific-aim:

- Brief Description of the Overall Approach
- **Study Population and Sampling**
- Data Collection Methods
- **Statistical Analyses and Power**
- **Limitations and Alternative Approaches**
- **Expected Outcomes**
- Timeline

Review considerations for analysis section

There are several crucial questions that will be asked by reviewers as they assess your design and analysis sections:

- 1) Are these the correct and best analysis methods for the specific questions?
- 2) Are the methods proven and properly cited?
- 3) Are the methods feasible given the time and support available?
- 4) Is the precision/power of the study appropriate and sufficient to answer your research questions?

* From Dan Gaylin:
www.pbrn.ahrq.gov/portal/server.pt?open=18...qid.

Other guidelines for analysis sections

PCORI Guidelines (General & Cross-Cutting)

1. **Assess Data Source Adequacy**
2. **Describe Data Linkage Plans, if Applicable**
3. ***A priori*, Specify Plans for Data Analysis that Correspond to Major Aims**
4. **Document Validated Scales and Tests**
5. **Use Sensitivity Analyses to Determine the Impact of Key Assumptions**
6. **Provide Sufficient Information in Reports to Allow for Assessments of the Study's Internal and External Validity**

Administrative Sections

- Budget Justification
- Biosketch (needed for Key Personnel)
- Resources

Budget Justification

- How much should be budgeted and what should your title be?
- The PhD on the grant will likely handle, but it might be useful for you to know some guidelines.

- Biostatistician – the title of the person conducting the data analysis for the proposal.
- Co-investigator – title of someone who is substantively contributing on all aspects of the study. Usually reserved for the PhD for new teams, but as you get embedded into a team.

Effort Allocation Guidelines:

A. Large or complex projects: Total biostatistics annual effort 50–100+% per year plus computational fees per FTE annually, such as 20% or more of PhD biostatistician plus 30–100% of an MS biostatistician:

- High level of involvement in the development and implementation of the research project and communication of study results, which may take many forms, including:
- Development and/or implementation of complex study designs.
- Assembly of datasets from large, complex or poorly documented sources (e.g. administrative or survey databases).
- Development and/or implementation of interim data analyses during data collection phase of prospective studies.
- Coordination of analyses for multi-site projects.
- Development of and/or use and interpretation of novel or complex statistical methods.
- Developing algorithms to identify units of analysis and define analysis variables

Active participation in publications, with opportunity for first authored papers.

B. Regular Projects: Total biostatistics annual effort 30–65% plus computational fees per FTE annually, such as 10–15% PhD biostatistician plus 20–50% of an MS biostatistician.

This effort profile is suitable for straightforward projects with uncomplicated analyses and includes:

- Collaboration and involvement of biostatisticians through all phases of the study, including regular meeting attendance.
- Involvement of biostatisticians in routine study design, implementation, and data collection.
- Well-documented primary datasets provided for statistical analysis
- Analyses carried out using off-the-shelf procedures available in statistical software packages.
- Active participation of biostatisticians in publications, with opportunity for first authored papers.

C. Simple Projects: Total biostatistics effort 20–35% per year plus computational fees per FTE annually, such as 5-10% of PhD Biostatistician plus 10-25% of an MS biostatistician.

- This effort profile is suitable for simple projects requiring minimal PhD biostatistician collaboration and straightforward statistical analyses performed by MS biostatistician (for about one manuscript per year).
- Ongoing occasional consultations with PI about study issues, such as choice of statistical methods to use. This level of effort is typically too low for a PhD-level biostatistician to carry out analyses or support regular attendance at weekly or biweekly project meetings by the PhD biostatistician.
- 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. Limited Scope projects: <10% biostatistician annual effort

Occasionally, a limited amount of biostatistician funding may be justified, for example, for assistance planning very small-scale Phase I trials or modest proof-of-concept animal studies, where some statistical analysis will be needed but the scope is limited. Very small projects may budget for biostatistics services using the approved biostatistics service center rate in place of personnel effort. Please discuss these unique situations with the biostatistician to determine the appropriate effort level and/or use of the service center rate.

Example Budget Justification

- **XXX , MS, Student Research Assistant** (12 calendar months Years 1-5 of a .5fte appointment). The student is a graduate student from the Department of Biostatistics and Informatics. She is currently an RA on Dr. Carlson's R21 application and is co-author on 2 abstracts with Dr. Carlson and Polotsky. She is trained to analyze pulsatile hormone data. She will be responsible for research data management, co-implementing the simulations in Aim 2 with Dr. Carlson, performing the analyses for Aim 1 and 3 under the direction of Dr. Carlson, including documentation and archiving of the analysis programs. She will draft statistical methods summary reports and data analysis reports for the clinical aims. She will create tables and graphics for the manuscripts.

- **TBN, Student Computer Programmer** (12 calendar months of a 0.5 fte appointment, Year 3-5) This position will be filled by a computer science undergraduate major at the University of Colorado Denver. They will be responsible for creating R statistical software and gui interfaces for the computer programs developed in this application. They will additionally be responsible for documenting the new statistical analysis programs, streamlining and improving code efficiency, and ensuring that the resulting compiled code for Aim 2 will be transportable across multiple platforms.

Example Budget Justification

Budget justification:

Dr. Jaron Arbet: Co-investigator (0.6 calendar months for Years 1, 2 and 1.2 calendar months for years 3 and 4).

- Dr. Arbet is a Research Associate in the Department of Biostatistics and Informatics and with the Center for Innovative Design and Analysis (the campus wide biostatistics collaboration unit). The research associate position is a PhD faculty position in the Colorado School of Public Health and used as the collaborative/team science focused track. He will be responsible for the overall statistical aspects of the proposal for Aim 2 and a consultant on Aim 1. The effort in years 1 and 2 are to attend team meetings, participate in any design modifications and assist with data base set up. For years 3 and 4, Dr. Arbet will conduct the data analysis, write analysis reports, and co-author the resulting manuscript. Dr. Arbet will assure that the data analysis is conducted in a reproducible framework and that statistical code and reports are documented.