

Guidelines for Including Biostatistical Support in IHRP Conducted Research Projects

This document describes guidelines and recommended procedures for incorporating adequate biostatistical and computational support on IHRP proposals and through the funding cycle.

Budgeting Guidelines

Identified biostatistician(s) should be involved early on in the grant submission process, and should be included in both the science and in budgetary decisions about biostatistician and graduate assistant FTE, computer and software purchases, and travel. Statistical expertise requires constant updating in intellectual and computing capacities. The benefits from cutting edge statistical and methodological expertise are shared and borne across all IHRP projects. A portion of the statistician's time may be spent on development of methods that are related to (though not essential for) a project.

The following guidelines are intended as a starting point for budget discussions with investigators. They include recommendations for 3 types of costs: co-investigator/biostatistician FTE; analytic support staff FTE; and, shared computing costs

The guideline percentages are intended to be constant over the lifetime of the grant. For multi-year projects, it might be reasonable to support statisticians and analytic staff at a lower FTE during data collection periods, after design issues have been settled and before analysis has begun. A minimum of 5% of biostatistician time should be budgeted in every year of a multiple year grant to assure continuity. Any changes in percent support made during proposal writing or after research has been funded should be made jointly between the PI and co-investigators/statisticians.

The following information serves as a guide to budgeting IHRP research proposals. Biostatistician FTE is tied to the level of involvement on the research. Research Assistant FTE is suggested for analytic support staff.

Level of Involvement	Biostatistician	RAs
Extensive	More than 20%	More than 50%
Regular	20%	25 - 50%
Limited	10%	Staff with consultation
Extremely Limited	5%	Project staff

Level: Extensive: 20% or more of an investigator/biostatistician
High involvement in the development and implementation of the research project, which may take many forms, including:

- a) development of and/or use and interpretation of new statistical methods
- b) development and implementation of complex study designs

- c) analysis and coordination of multi-center projects
- d) active participation in publications, with opportunity for first authored papers
- e) project-related travel and external presentations.

Analytic staff: A research specialist or qualified graduate assistant at 50% or more FTE is recommended for this level of involvement

Level: Regular: 20% of an investigator/biostatistician

- a) Active participation in publications, with opportunity for first authored papers
- b) Involvement in study design, implementation and data collection
- c) Routine study design and analysis, e.g., analyses carried out using standard statistical software

This percentage is suitable for uncomplicated analyses

Analytic staff: A research specialist or qualified graduate assistant at 25% or more FTE is recommended for this level of involvement

Level: Limited: 10% of an investigator/biostatistician.

- a) Involvement through consultation with the PI about choice of statistical methods and advising of the analytic staff, limited statistical analysis.
- b) Co-author on papers, but not enough involvement or time to write a first-authored paper.

This percentage is realistic in some cases, but is too low if the statistical analysis is at all complicated. Meetings attendance may be infrequent and restricted to discussion of statistical issues.

Analytic staff: A dedicated project staff member to perform data management and simple analysis under the supervision of the PI is recommended.

Level: Extremely limited: 5% of an investigator/biostatistician

- a) Consult with PI about choice of statistical methods to use, but not enough time to carry out analyses
- b) Supervise a faculty or staff member who is funded at 25% or more FTE to carry our analysis

The biostatistician provides consultation to the PI who is responsible for analysis. This FTE level is too low to support regular meeting attendance, but may be appropriate for NIH K-series awards, post doctoral and investigator training grants.

Analytic staff: A research specialist or qualified graduate assistant at 25% or more FTE is recommended to assist the PI to conduct all analytic tasks.

Procedures for Including Biostatistical Support in IHRP Conducted Research Projects

The need to provide appropriate levels of support is driven by the dual responsibilities of investigator-biostatisticians in a multi-disciplinary research enterprise. One is to support the research of other investigators at the Institute. The other is to stay connected to statistical research through their own work and be current with emerging statistical methods and techniques. The latter is essential for funding and growth of the Institute. In addition, statistician-investigators need first-authored and co-authored papers for career growth.

The process for working with a biostatistician is similar to the process involved when working with any scientific staff. Basic steps are outlined below.

1. **Get the biostatistician involved early.** Begin looking for a biostatistician to collaborate with shortly after deciding to submit a grant. You can find a biostatistician one of two ways:
 - a. Directly contact a biostatistician that you would like to work with and ask them to participate on your project, or
 - b. Contact Mike Berbaum, Director, Methodology Research Core and work with him to identify an appropriate biostatistician.

MRC biostatisticians strive to meet the statistical needs of the Institute. However, it is possible that on occasion there will not be sufficient staff to meet these needs. It is possible that on some occasions, the biostatistician you work with to write the grant would later be replaced in order to more equally distribute the workload of the MRC. Any change would be accomplished with mutual consent of the PI and MRC Director.

2. **Plan an initial meeting.** The following items should be discussed at this meeting, or at least very early on in the grant planning process.
 - a. Discuss the overall study design and hypotheses, and begin discussion about the scope of statistical work. The scope of planned work determines both appropriate FTE levels and the amount of work required to write the statistical sections of the grant. Institute guidelines regarding biostatistician FTE on grants identify 4 general levels of involvement:
 - 1) “extensive” - complicated analyses that may require development of new statistical methods;
 - 2) “regular” - straightforward analyses;
 - 3) “limited” - primarily consultation with project team; and
 - 4) “extremely limited” - primarily used for limited consultation with a PI or supervising a junior researcher who carries out all work.
 - b. Decide on the biostatistician’s specific responsibilities and other expectations. The level of detail provided by a statistician can vary widely across projects and investigators. For example, responsibilities can

include carrying out sample size and power calculations, writing the analysis and sample size sections, and contributing to multiple sections of the grant. During project development the biostatistician should be included in meetings as appropriate and be made aware of developments as the projects unfolds. Expectations for biostatistician involvement during the implementation of the project (meeting attendance, contributions to papers and presentations) should be made explicit.

- c. Discuss research specialist/assistant requirements. Many tasks such as data management and documentation, simple analysis and preparation of data for presentations can be effectively performed by junior staff including research specialists and graduate assistants under the supervision of a senior biostatistician. Utilizing junior staff to perform routine work reduces the burden on senior staff and can have positive budgetary consequences. Care must be exercised to employ only appropriately trained students and staff to assist in analytic tasks. MRC biostatisticians can advise on the use of appropriately trained students and academic staff.
- d. Discuss the budget, including
 - 1) Planned biostatistician FTE level based on the expected scope of work
 - 2) Use of trained research specialists and assistants as appropriate
 - 3) Equipment and software needs
 - 4) Travel

Guidelines for incorporating appropriate biostatistician and graduate assistant support, computer, and other costs are provided below.

- e. Discuss timelines and determine information that is needed to carry out task such as sample size calculations.

- 3. Continue communication throughout the grant writing process and during all phases of the research.** Discuss revision of planned tasks and assess progress. Once the grant is submitted, provide a final version of the proposal and of relevant budget items (FTE levels, travel, software, computer) to the biostatistician. Once the project has begun the biostatistician should be informed of any changes that affect the study design, sample selection, data collection, etc. The methods for informing the biostatistician will differ depending on level of involvement. If biostatistician involvement is extensive, regular meetings will convey the necessary information. If engagement is limited, active information sharing by the PI or designated staff is required.

Principal investigator's responsibilities

In addition to determining a grant's primary aims and writing the bulk of the grant, the PI is responsible for communicating with the biostatistician by:

1. Providing drafts of the grant as it evolves, even if the biostatistician is not writing specific sections
2. Providing information required for sample size and power calculations in a timely manner.
3. Communicating relevant budget plans, and changes to these plans. Planned FTE levels should be communicated at least one month before the grant is submitted. Any changes to planned travel money, software, or equipment budgets also need to be discussed with the biostatistician before the grant is submitted, even if these are last minute changes. **Changes to grant FTEs for statistical faculty and staff after the project is funded or in future years should be made jointly by the PI and co-investigators/statisticians, communicated in writing to the relevant individuals, and copied to the grant manager and human resources staff.**

Additional Considerations

Authorship on papers:

- Authorship on papers should be discussed early. Usually a statistician working 10% or more on a project will have contributed enough to the research to be a co-author on papers. Authorship is also merited for supervising statisticians who guide the analyses carried out by researchers.
- An investigator-biostatistician working 20% or more on a project should have the opportunity to write one statistical methods paper and/or first-author a substantive paper.

Other Budget Items: Travel, Computing, Training:

- The need for computers and software should be discussed with the named statistician. Specialized software may be also required for some projects.
- Attendance at statistical meetings is critical to maintaining statistical expertise. Project-based travel funding should allow for one to two statistical meeting per year per FTE. For example, 25% FTE biostatistician should budget for attendance at one statistical meeting every other year. Funding at lower FTE's can partially support meeting attendance by paying for either airfare or hotel and registration. Workshop attendance can be an important way for biostatisticians to continue their professional growth. In some cases, workshops (often offered in conjunction with statistical meetings) may be needed to gain statistical tools needed to carry out required analyses.

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