# [Guidelines for Including Biostatistical Support on Illinois Conducted Research Projects](https://uillinoisedu.sharepoint.com/%3Aw%3A/s/BiostatsCore/EfTVg9SvlBJMsMH-CZQfKQQBLVWQxysZtB3KtUWRoaYI9Q?e=UoIurT)

The following guidelines are intended as a starting point for budget discussions with investigators. They include recommendations across four levels of collaboration: extensive, regular, limited, and extremely limited.

**Billing**: Hourly vs. % FTE: The most appropriate way to include the Illinois BERD team on your grant depends on their level of involvement. All services are charged hourly. The team can either be listed as a service, or one or more of the biostatisticians can be included as key personnel/co-investigator. The expected hours of services can be translated into % FTE (e.g., 5% FTE = 2 hours a week or 104 hours per year) for ease of inclusion in the budget.

**Level of collaboration**:

*Level 1 – Extensive:* More than 104 hours per year/2 hours per week

High involvement in the development and implementation of the research project once the award has been made, suitable to large grants such as R01, U01 and P grants. Collaboration may include the following biostatistical services:

1. Project conceptualization including formulation of research questions and objectives
2. Development of standard and complex study designs
3. Calculation of sample size and power analysis
4. Active coordination in project implementation including oversight of data collection
5. Creation of analysis datasets from compiled and clean data from experiments, clinical trials, epidemiologic studies, surveys, and existing large databases
6. Preparation of detailed statistical analysis plan including the application and development of new and advanced statistical methods
7. Performance of Interim and full data analyses and limited post-study secondary data analysis
8. Preparation of tables and graphs for publication
9. Active participation in publications, with opportunity for first authored papers
10. Potential project-related travel and external presentations
11. Oversight of compliance to data sharing requirements

*Level 2 – Regular:* 52-104 hours per year/ 1-2 hours per week

This effort profile is suitable for straightforward projects with uncomplicated analyses.

1. Enumeration and clarification of specific research questions and objectives
2. Development of routine study designs
3. Calculation of sample size and power analysis
4. Minimal oversight of data collection and encoding
5. Preparation of detailed statistical analysis plan covering analyses carried out using standard statistical software
6. Creation of analysis datasets from compiled and clean data from experiments, clinical trials, epidemiologic studies, surveys, and existing large databases
7. Performance of interim and full data analyses
8. Preparation of tables and graphs for publication
9. Active participation in up to 5 papers for publications, with opportunity for first authored papers Oversight of compliance to data sharing requirements

*Level 3 – Limited:* 25-52 hours per year

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

1. Specification of limited scope of research questions and objectives covered by biostatistical services
2. Involvement through consultation with the PI about choice of study design and statistical methods
3. Calculation of sample size and power analysis
4. Preparation of statistical analysis plan
5. Creation of analysis datasets from compiled and clean data from experiments, clinical trials, epidemiologic studies, surveys, and existing large databases
6. Performance of limited statistical data analysis
7. Preparation of tables and graphs for publication

*Level 4 – Extremely Limited*:

If the PI has some funds and their need is at the ‘extremely limited’ level, they can budget for statistical consultation at an hourly rate for a minimum of 6 hours. Consultation services include discussion of research questions, and objectives, study design, and statistical methods. The core can provide guidance but will not perform actual statistical analysis.

# Procedures for Including Biostatistical Support and Ensuring Successful Collaboration in Research Projects

1. BERD biostatisticians strive to meet the statistical needs of the researchers at UIUC. Projects are considered on a first come first served basis. It is possible that the biostatistician you work with initially to write the grant could be replaced with another. Any change would be accomplished with mutual consent of the PI and the collaborating biostatistician.
2. Get the biostatistician involved early. Begin looking for a biostatistician to collaborate with as soon as you decide to submit a grant. Complete the Project Initiation Form (PIF) to begin this process.
3. Initial consultation meeting:
	1. Discuss the overall study design and hypotheses, and begin discussion about the scope of statistical work:

1) Extensive – Co-I or Principal biostatistician role, extensive involvement in all stages of the project, complicated analyses that may require development of new statistical methods, post-study involvement (presentations, limited secondary data analysis)

2) Regular – Co-I or Principal biostatistician role, contribution to statistical aspects in proposals and publications, regular attendance in research team meetings, involvement in selected phases of research, analysis using standard software, co-authorship in publications

3) Limited – Possible key person role as biostatistician, primarily consultation with BERD staff, infrequent meetings with research team, limited data analysis, co-authorship in publications

4) Extremely limited – no involvement as key person, primarily consultation with BERD staff

* 1. Decide on a budget based on the level of collaboration. BERD Core’s finance officer can provide a letter of support, and a budget agreement.
	2. 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 project unfolds. Expectations for biostatistician involvement during the implementation of the project (meeting attendance, contributions to papers and presentations) should be made explicit.

* 1. Discuss timelines and determine information that is needed to carry out tasks such as sample size calculations.
1. 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, and database) 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 the 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/access to 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.
4. Ensuring that the project has sufficient BERD budget for the required deliverables.
5. Sharing with the biostatistician comments of reviewers on statistical aspects of proposals and submitted papers for publication.
6. Providing BERD with a final copy of the research proposal approved by the funding agency.
7. Including biostatistician/s as co-authors in publications if the biostatistician meets the required contribution as stipulated in the ICMJE/JAMA. If BERD contributions do not meet criteria for co-authorship, PI should acknowledge BERD contribution to the paper.

Statistician’s responsibilities

1. Conveying what they need to be able to compute the sample size calculation and the statistical analysis plan in writing to the PI.
2. Providing a detailed budget justification and list of deliverables with a timeline. Any materials needed to provide the deliverables need to be clearly written.
3. Supervising the writing of a clear data management plan and ensuring that resources are dedicated to this task to be able to produce the above-said deliverables.
4. Delivering the agreed upon statistical outputs to the PI or PI’s representative.
5. Attending meetings that require biostatistician participation and input.
6. Providing letter of support or letter of collaboration to PIs.

# 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 40 hours or more on a project should have the opportunity to write one statistical methods paper and/or first author a substantive paper.