

CTSC/BERD Biostatistical Core and Support Guidelines

Thanks to the NIH Clinical and Translational Science Award to UNMHSC, the Biostatistics, Epidemiology, and Research Design (BERD) Core of the UNM HSC Clinical & Translational Science Center (CTSC) is able to provide expert biostatistical support to UNM HSC investigators. The support covers all quantitative aspects of a research project with administrative categories of *Consultation* and *Service*.

The BERD Core provides easily accessible consultation and services, user-friendly courses for researchers at all levels, and novel tools and methods intended to solve problems and address barriers to the conduct of clinical and translational research. Our services are open to all UNM-HSC investigators (staff, students, and faculty) to understand the methodological aspects of their research for planning their projects, including power analysis, sample size, and research design for extramural grant submissions. Below is key information related to our core.

- a. **Consultation** is designed to plan for a pilot study, grant application, or data analysis project. The biostatistician may perform the required work outside the face-to-face meetings with the investigator.

Consultation activities include:

- Study designs and data elements relevant to the study hypotheses
- Simple sample size calculations or power analysis
- Writing of relevant sections for grant proposal submissions
- Writing statistical analysis plans and strategies

- b. **Service** generally covers in-depth work required for the research project. During the initial consultation, the biostatistician shall provide an objective estimate of the amount of effort needed to complete the proposed work. The biostatistician should communicate with the investigator if the estimated amount of effort changes due to changing requirements of the project or due to unanticipated complexities.

Service activities include:

- In-depth statistical analysis and modeling
- In-depth work to prepare for a grant application (e.g. analysis of pilot data, sample size calculation based on complex models)
- Ongoing work on a continuing project
- Results dissemination including writing of abstracts, papers and presentations, and responding to reviewer comments
- Research for specialized methods required for a specific project

GME Investigators (residents & fellows) – Biostatistical support is available free of charge to residents and fellows through departmental/institutional funds. Only projects on which residents or fellow serves as Principal Investigator (PI) qualify. Projects that involve a resident or fellow with a faculty member serving as the PI does not qualify.

BERD Appointment and Billing Policies

- a. **Setting Appointments:** Please contact HSC-CTSCbiostats@salud.unm.edu to schedule appointments and complete the required paperwork (Request for Biostatistics Service form). Please do **not** contact biostatisticians directly for scheduling appointments.

Some Tips for Scheduling

- Appointments for initial *consultation* are generally limited to one hour.
- You should schedule a meeting with a biostatistician as early as possible in the process of protocol development. For grant applications, we request at **least 4 weeks** or more ahead of internal grant

- deadlines. The biostatistician can assist you with study design and with writing a statistical analysis plan and its essential components, like specifying sample size.
- Large amounts of consulting hours over a few days or weeks is likely to not be possible or practical. We will do everything we can to accommodate your project, though please be aware that CTSC biostatisticians may be 1) working with many other investigators at different stages of their research, and/or 2) need time to work through complicated biostatistical analysis.
 - During the initial meeting, develop a work plan and timeline with the biostatistician and make regularly scheduled appointments. It is not practical trying to schedule a large amount of work in a short period as the biostatisticians work on multiple simultaneous projects.
 - Late proposals: Grant application assistance requested less than 4 weeks prior to the grant deadline may only be expedited with a waiver from the CTSC Biostat Core Director, Dr. Yiliang Zhu (YiZhu@salud.unm.edu). For instructions regarding requesting a waiver, please email HSC-CTSCbiostats@salud.unm.edu.

What to Bring to a Meeting

Some of the information you should bring to a meeting with the biostatistician includes:

- A clear articulation of your study question and hypothesis
 - Relevant papers where similar variables have been studied
 - Any pilot data you may have
- b. **Billing Policy:** All billable work will be charged at \$75/hour and an index number will be required for invoicing purposes. Minimum billing is 1 hour, with increments of 30 minutes after the first hour. Billing hours include time spent in face-to-face meetings with the investigators as well as work performed outside the face-to-face meeting hours.
- Each UNMHSC faculty investigator receives up to 5 hours of consultation per calendar year, cost paid for by CTSC. **After the 5 CTSC-sponsored consultation hours or when the work enters the phase of service, whichever comes first, hours will be billed accordingly.**
- c. **Cancellation Policy:** In order to utilize the BERD biostatistics resources efficiently, the CTSC requests a minimum of **48 hours** notice of cancellation. Cancellations within 48 hours or no shows will incur the same billing as that for the reserved appointment, after 2 no shows.

Authorship Policy:

CTSC/BERD requires that the BERD biostatistician serve as a co-author on publications involving BERD biostatistical support if he or she meets the criteria set forth by the International Committee of Medical Journal Editors (ICMJE) as follows:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CTSC/BERD also requires that the BERD biostatistician serves as a co-investigator or named biostatistician on grants that are developed with the BERD biostatistical support. The level of commitment should be discussed and mutually agreed upon between the PI and the biostatistician.

CTSC Biostatistical Financial Support

1. If you do not have funds available from extramural grants, we encourage you to seek funding from the CTSC Pilot Program, HSC Research Allocation Committee (RAC), and/or departmental sources.
2. Support for GME residents' research projects is also provided through Departmental/Institutional support. Residents do not need to provide a billing account number.
3. We can provide language and supportive documentation for CTSC biostatistical support for your grant applications.
4. CTSC Pilot Project funding is an important potential mechanism to gain additional support for biostatistical support services.
5. Biostatistical support for Cancer Center projects is provided by the Biostatistics and Bioinformatics Shared Resource of the UNM Cancer Center.
6. Biostatistical support for medical student research projects required for graduation is provided by the Office of Undergraduate Medical Education.

If your study used CTSC resources for any part of a proposal, paper or presentation, please acknowledge the CTSC NIH award number: **UL1TR001449** AND include this number in your PubMed Central (PMC) attributions for any manuscript.

Additional Information

For further information, please contact:

- **BERD Director-** Yiliang Zhu, PhD
 - Email- Yizhu@salud.unm.edu