

CTSI Biostatistics, Epidemiology, and Research Design (BERD) Consulting Unit Frequently Asked Questions

December 10, 2019

Q1: What is the CTSI BERD Consulting Unit?

A: The CTSI BERD Consulting Unit is a component of the Biostatistics, Epidemiology, and Research Design (BERD) Program of the Clinical and Translational Science Institute (CTSI). It is designed to provide collaborative advice and services in the areas of **study design, data analysis, and data management**. It is a collaboration between the CTSI, the Department of Biostatistics and Data Science, and the Department of Epidemiology and Prevention. Both departments are in the Division of Public Health Sciences. The BERD Consulting Unit is directed by Joseph Rigdon, Ph.D. (336-716-1048, jrigdon@wakehealth.edu), and Gregory Russell, M.S. (336-716-5449, grussell@wakehealth.edu).

BERD Consulting Unit services include both pre- and post-award work, and will be tailored to the investigators' needs. Pre-award work may include assistance with study aims and hypothesis development, choice of study design, choice of statistical methods, sample size estimation, and writing the statistical sections of applications. Post-award work may include data entry and management, data analysis, interpretation, and preparation of results for publication and presentation. These tasks would usually be done to support small projects, or those for which a sustained collaborative relationship is not required.

If your project seems to be a good fit for the BERD Consulting Unit, please fill out a request form at <https://ctsi.wakehealth.edu/About-CTSI/Service-Request>. Select "Biostatistics Core". For grant development, select "Pre-award" and for data analysis select "Post-award." Please make every effort to **fill out the service request form 60 days prior to needing a deliverable**.

Q2: What is the funding model for the BERD Consulting Unit?

The BERD Consulting Unit operates on a **fee-for-service model**. The BERD Consulting Unit is not a replacement for the collaborative research done in the Departments of Biostatistics and Data Science (BDS) and Epidemiology and Prevention (EPI) but an alternative arrangement for projects with more limited involvement of BDS or EPI faculty and staff. We generally spend less time on a project that comes through the BERD Consulting Unit than if we were receiving FTE-based support. Whether an individual project should be handled through the BERD Consulting Unit or through BDS/EPI as an FTE-based collaboration will be discussed.

Q3: What about authorship for our collaborations?

A: Authorship is completely independent of funding. **If we make a contribution that warrants authorship, then we expect to be listed as an author(s)**. The International Committee of Medical Journal Editors (ICMJE) authorship is based on

substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND 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.

Full description of ICMJE guidelines is available here:

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

Q4: What BERD Consulting Unit resources are available at no cost to me?

A: For all WFSM faculty, assistance with grant development is provided for free, **provided that BERD is included in the budget**. For early career faculty (<https://ctsi.wakehealth.edu/early-career-faculty>), we also provide free assistance with data analysis for papers and abstracts. **If our involvement includes assistance with a grant which would, if funded, make the early career investigator no longer eligible for free analytic support, then we must be included in the budget.**

Q5: What are the rates for post-award work?

A: All post-award work will be billed at an hourly rate with the exception of qualifying early career faculty. This includes data entry, data management, meetings, data analysis, programming, writing, editing, paper revisions, etc. Hourly rates for the 2020 fiscal year are shown in the following table. These rates cover salary, fringe, and computing expenses. These rates do *not* include indirect costs. Rates will be adjusted annually, and projects will be charged the current rates in effect when work is performed.

FY2020 BERD Rates	Hourly Rate
Faculty	\$145
Staff	\$95

We will evaluate rates annually, aligned with the fiscal year, i.e., rates will be evaluated every May/June for the fiscal year starting July 1, and will change them if necessary. The CTSI will generate monthly bills.

Q6: What if I have a simple power calculation?

A: We have developed a set of web-based power calculators available at <http://power.phs.wakehealth.edu/>. SAS is used behind the scenes as the computational engine. Existing designs include correlation, one-sample *t*-tests, two-sample *t*-tests, paired *t*-tests, one-sample frequencies, two-sample frequencies, and paired frequencies. Also available is a series of questions to aid investigators in the selection of calculator. We also recommend two free programs that can be downloaded from the web, G*Power (<http://www.gpower.hhu.de>) and PS (<http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize>). As always, we encourage investigators to consult with a statistician when there are questions about these calculations.

Q7: What do BERD Consulting Unit personnel need to help me?

A: If we are assisting with a grant, we will need a description of all available pilot data, a draft of the specific aims, proposed study design, an idea of the feasible sample size, and any other relevant information. If we are assisting with data analysis, we will need the data electronically (in a format such as an Excel spreadsheet, we will be happy to discuss how best to do this) and the questions of interest. **If your data contain protected health information (<https://www.hipaajournal.com/what-is-protected-health-information/>), we ***MUST*** be added to your IRB.**

Q8: What do I need to submit a grant with the BERD Consulting Unit?

A: We will work with you to establish a scope of work and will budget accordingly. If there is only a fixed amount of money available, we will discuss what can be accomplished for that amount. Once we've agreed on a budget, you will receive a letter of support from Joseph Rigdon which will include the budget estimate for BERD support. The letter will be written so that it can also serve as a letter of support; you are welcome to submit it with your grant.

Q9: What do I include in a grant submission?

A: We will provide a brief budget for BERD services for the budget as well as a complete description for the resources section. Please note that we generally do not provide NIH biosketches for BERD effort.

Q10: What happens after my grant is funded?

A: Please email Joseph Rigdon (jrigdon@wakehealth.edu).

Out of mutual respect for our collaboration, **please do not cut us from the budget after funding.**

Like most researchers, we much prefer conducting studies to writing the grants which pay for the studies. If we help to design a study which gets funded, then we have held up our end of the bargain. Cutting us out of the budget after a grant is funded deprives us of the most interesting part of our job, hurts us academically (no publications), and does not foster productive long-term relationships.

Q11: What if the grant budget is cut by the funding agency?

A: We are well aware of and understand that entire grant budgets get cut. If a grant gets cut by 20% then it would be reasonable for the BERD to be cut by 20% but not reasonable for us to receive a disproportionately larger cut. Of course, we will have to discuss how budget cuts affect the work we can perform.

Q12: What if this is for a protocol to be submitted to the Comprehensive Cancer Center or the Older Americans Independence (Pepper) Center?

A: Please contact those groups directly. For the Cancer Center, please contact Ralph D'Agostino, Jr., Ph.D. (336-716-9011, rdagosti@wakehealth.edu). For the Pepper Center, please contact Mike Miller, Ph.D. (336-716-6837, mmiller@wakehealth.edu).