

STANDARD OPERATING PROCEDURES

The mission of the UCI Institute for Clinical and Translational Sciences Biostatistics (ICTS) Epidemiology, Research and Design (BERD) Unit and UCI Center for Statistical Consulting (CSC) is to enable UCI investigators and affiliates to conduct and communicate research of the highest possible quality. The primary activities of the unit include:

- Statistical support for grant submissions
- Statistical and design issues for new and ongoing studies
- Statistical analysis of data and consultation
- Development of clinical and experimental research protocols
- Manuscript writing and revisions assistance
- General Statistical Consultation

BERD/CSC has been involved in the data analysis of a wide variety of projects, including clinical and epidemiology studies, assessment of diagnostic methods and treatment modalities, clinical trials, observational research, predictive modeling, causal inference, mediation, reliability/validity, survey data analysis and the development of novel statistical techniques. Priority will be given to UCI and UCI affiliated researchers. Consulting on projects for external (non-UCI or non-UCI affiliated) entities will be considered on a case by case basis. This document describes the standard operating procedures (SOP) for statistical consulting and for recharge/billing policies. For information regarding billing administration, contact Sarah Cushing Britigan, ICTS Fiscal Officer, scushing@uci.edu or Jodi Macgregor, jmacgreg@uci.edu, CSC Business Manager.

Research Assistance

Please Note: The initial first hour of consultation is free for researchers and affiliates. The first hour free policy is intended for use for consultations on potential long term collaborations between BERD/CSC and researchers. The first hour of consultation between the researcher and BERD/CSC staff is designed to determine the researcher's needs and assess the scope of the project, it is not designed to address general analysis questions. As part of our long term collaboration planning, consultants may take up to 1 hour to review any project-related documentation ahead of the initial consultation. Any time needed beyond this will be charged to the client. If you have a general statistical or data analysis related questions, please use our BERD drop-in session, you can sign up for an appointment [here](#).

Grant preparation:

An important function of the BERD/CSC is to provide assistance to all investigators and co-investigators with grant preparation for research studies. The following policies and guidelines for new grant preparation will apply:

1. Submitted grant budgets should include the following for future statistical services: (1) percent effort for one or more named statisticians from the BERD/CSC, or (2) a budget allocation for statistical service to be paid on the basis of recharge.
2. The BERD/CSC statistician(s) will be given at least 8 weeks to work on the submission prior to its due date and will be involved in all aspects of study development, including, but not limited to, study design, determining measures and outcomes, sample size calculations and data analysis.
3. The BERD/CSC statistician must review the final grant application prior to submission to ensure consistency in the design, analysis and sample size consideration sections as well as ensuring that reasonable funds for statistical support are allocated in the event of funding.
4. BERD/CSC statisticians do not charge for assistance with grant preparation for **UCI-affiliated researchers or academic/non-profit external clients** if the statistician will be included as an investigator or named statistician and thus funded through the grant.

1. The level of commitment should be discussed and mutually agreed upon between the PI, the statistician and the CSC/BERD director.

Power analysis: BERD/CSC statisticians can be used to perform the power analysis for grant proposal as well as IRB applications. This service will have the same expectations associated with it as standard data analysis projects which are described below.

Data analysis and abstract, manuscript, and presentation preparation: The BERD/CSC also will assist UCI researchers and affiliates with data analyses and preparation of abstracts, papers, and presentations. The following policies and guidelines will apply:

1. The principal investigators (PI) and/or appropriate research staff will consult with a member(s) of BERD/CSC to assess the statistical needs of the project.
2. After the consultation a statistician will draft a Scope of Work (SOW), to be provided to the investigator, which details the expectations of the work to be performed including:
 1. A descriptions of the project
 2. Timeline including estimated deadline(s)
 3. Estimates hours and cost or expected % effort
 4. Agreed upon project deliverables (methods section write-up, tables, analysis description etc.)
 5. Expectation of authorship. Please see our guidelines on authorship below.
 6. Hourly recharge rate or % effort
 7. Payment options
 8. Contact information for BERD/CSC and PI fiscal officer
3. The SOW must be signed by the PI:
 1. PLEASE NOTE: Work on the project will not start until the SOW has been agreed upon and signed by all necessary parties.
 2. UCI-affiliated projects require the designation of a KFS account number for recharge.
 3. Non-UCI projects require contact information (including email and/or mailing address) where invoices are to be sent. Payment by check will be made to "UC Regents."
4. The statistician performing the analysis will be a co-author on the publication to acknowledge the intellectual contribution to the work, if appropriate. Please see our guidelines on authorship below.
5. Statistician co-authors will use their primary appointment affiliation on manuscripts and abstracts.
6. Co-authorship will not be considered in lieu compensation.
7. The statistician will be given at least 1 week to review any final drafts of an abstract or publication prior to submission or resubmission in order to ensure study and statistical integrity.

Data Policy:

Data submitted must be complete and in a format that requires no or minimal pre-processing and quality control ("cleaning"). If the data requires significant data management the time needed for the consultant to process the data for analysis will be charged to the client. In addition, BERD/CSC cannot accept data with personally identifiable information (PII) included. It is incumbent upon the researcher to remove any PII from the data before it is provided to the statistician. Failure to do so may result in a delay in the start of the project until this issue has been resolved. For information on what constitutes PII please go the UCI Information Security and Privacy [page](#).

Note that "hiding" columns in Excel or any other database manager does not constitute removal. All columns with PII must be deleted/removed.

BERD/CSC will ensure that data is housed only on devices managed by UCI and will therefore abide by all information security protocols therein. BERD/CSC also assures that data received will not be used for any purposes other than the work agreed upon above unless authorization is received from the client.

Acknowledgment and Authorship Policy:

If your study used BERD/CSC resources for any part of the proposal, paper or presentation, please acknowledge the CSC or BERD.

BERD/CSC requires that the statistician be offered authorship on publications involving BERD/CSC statistical 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.

The services of BERD/CSC statisticians should be acknowledged in all publications and presentations if they made contributions to your project, but do not meet criteria for authorship. To avoid misunderstandings please discuss authorship early in your relationship with the statistician and include this information in the SOW. Note, the consulting statistician reserves the right to decline authorship when offered.

Payment options:

If the investigator wishes to utilize the services of a BERD/CSC statistician, the investigator can choose from the following service models:

Recharge/Fee-for-Service Model (Hourly Rate): Rates are \$100/hr for UCI-affiliated researchers, \$130/hr for academic/non-profit external clients and \$150/hr for for-profit or commercial clients (rates are subject to change). Once the scope of work has been agreed upon by the investigator and BERD/CSC statistician and memorandum of understanding signed, the investigator will be billed on an hourly basis until the completion of the project. In order to be eligible for our internal rate of \$100 you must use an UCI Internal KFS account for payment. If you are UCI-affiliated but using a non-KFS account or paying out-of-pocket for consultation, then you will be charged an external rate (either \$130 or \$150) that is contingent upon your primary affiliation for the project. For example, if you have dual affiliation with UCI and CHOC but CHOC funds will be used to pay for services then you will be charged our external academic/not-for-profit rate of \$130. However, if you are a UCI researcher but the funding for your project is coming from an outside for-profit company you will be charged our external for-profit rate of \$150.

* Registered UCI Student who pay "out-of-pocket", will be charged the internal UCI rate of \$100/hr.

Grant Support Model: The goal for providing grant support at no cost is to cultivate a collaborative environment that will lead to successful grant applications. For grant applications that BERD/CSC staff help prepare and write, it is expected that the principal investigator will invite BERD/CSC statistical analysts to be included for % effort as appropriate. BERD/CSC involvement from the initial steps of the application helps ensure that study design, data analysis, and power analysis are appropriate and optimal, and increases the chances that the grant will be funded.

Subscription Model: Departments or investigators that require some statistics support may "subscribe" to a portion of a BERD/CSC staff time. Those requesting this model must agree to fund a portion of % effort for at least 6 months. **The minimum percent effort for use of this model is 20%.**

* Please note the fee-for-service model is the only option available to external clients (non-UCI affiliates) unless a grant sub-award has been executed.

Time Frame:

Please contact the BERD/CSC as early as possible before your deadlines and with an awareness of the following guidelines:

1. You should schedule a meeting with a statistician as early as possible in the research process. It is important to note that most projects require at least 6 week notice prior to the requested final deadline. If your project has an earlier deadline (e.g. less than 6 weeks from date of the initial request for consultation), we encourage you to make a consultation request, but please note that we may be unable to accommodate earlier deadlines. Projects, depending on the complexity, may range from a few hours to many months to complete so please plan ahead.
2. As deadlines approach, the likelihood that we can provide helpful statistical support diminishes. On a case by case basis, the BERD/CSC may decline requests that are too close to the deadline to provide meaningful assistance.
3. Because there are always competing demands for statistical support, investigators are expected to work with us to help meet their deadlines. Any timelines set for providing data and protocol drafts, or otherwise disseminating necessary information must be strictly adhered to, or a revised timeline will need to be established.
4. It remains the responsibility of the investigator to ensure that all activities move forward according to the timeline required for the project. The BERD/CSC will endeavor to satisfy investigators' needs, but cannot be expected to satisfy unrealistic deadlines.

Manuscript Revisions:

We understand that manuscripts developed with the assistance of BERD/CSC may require revisions after submission for publication. The need for revisions can be handled in one of several ways:

1. If the subscription or grant support model is active, necessary revisions are covered under the initial agreement regarding % effort.
2. If the subscription or grant support model is no longer active, or the original project agreement designated under the fee-for-service model has ended, then a new SOW must be enacted to cover the cost of the additional hours needed by the statistician to complete the necessary revisions and/or perform any additional analyses.

Assistance with dissertations or theses:

Graduate students are permitted to use BERD/CSC services. However, if a graduate student wishes to enter into a formal agreement to obtain data analysis assistance from a statistical consultant, BERD/CSC require that the student's primary faculty advisor contact BERD/CSC directly acknowledging awareness of the student's choice to access our services for the purposes of their dissertation or thesis. Note, that we do not offer assistance with course work or qualifying exams.

Statistical Financial Support:

1. If you do not have funds available from extramural grants, we encourage you to seek funding from departmental sources or ICTS project grants.

Please Note: If you are a graduate student, staff researcher or faculty member in the School of Biological Science, CSC may be able to provide assistance for all or a portion of your project at no charge. Please contact us for further details.

2. We can provide language and supportive documentation for BERD/CSC statistical support for your grant applications.

For further information, please contact: • BERD/CSC Director- Joni Ricks-Oddie, PhD • Email- jricksod@uci.edu

To schedule a consultation with BERD/CSC please use the following links:

BERD: <http://www.icts.uci.edu/services/berd%20request.php>

CSC: <https://statconsulting.ics.uci.edu/request-consultation/>