

STANDARD OPERATING PROCEDURES

The UCI Institute for Clinical and Translational Science (ICTS) has established the Biostatistics, Epidemiology, Research and Design (BERD) Unit and Center for Statistical Consulting (CSC) to assist UCI investigators and affiliates to conduct and communicate research of the highest possible quality. The primary activities of the units include:

- Database creation and management
- Statistical support and study design for grant submissions
- Statistical and design issues for new studies
- Statistical analysis of data and consultation
- Predictive modeling analytics and machine learning
- Development of clinical research protocols
- Manuscript writing and revisions assistance
- Statistical programming and methodology
- Drop-in consultations

BERD/CSC are 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 is given to UCI researchers. Consulting on projects for external (non-UCI) entities are 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, please contact Sarah Cushing Britigan, ICTS Operations Manager, at scushing@uci.edu, or Margaret Erel, CSC Business Manager, at merel@uci.edu.

Important Information for Researchers

Consulting Rates and Budgets:

Hourly rates are subject to change on an annual basis. We recommend researchers factor in 10% cost increases each year to keep pace with inflation and salary increases.

Deadlines:

Deadlines should be realistic. Please consider the time needed to review, adjust statistical methods as needed, and follow up.

Federal Grants:

Per federal funding policy, we are unable to work on grants that have expired. Researchers are responsible for requesting assistance well in advance of the grant expiration date. Please consider the full scope of the project when planning.

Complex Data Sets and Data Management:

Large complex databases often require a considerable amount of data management. The extra time necessary to create an analyzable dataset can significantly increase the cost of the project. Datasets like All of Us and TriNetX that have their own user interfaces have not been designed to allow for easy analysis and we have found them challenging to use. We will discuss the complexities and challenges of any large database with you so that you are fully informed at the beginning of the project.

Prepayments:

We do not accept prepayments under any circumstances.

Free Hour Policy:

The first hour of consultation between the researcher and statistician is free for all clients. This first hour is intended for consultations on potential long-term collaborations between BERD/CSC and researchers. This initial consultation is to determine the researcher's needs and assess the scope of the project, deadlines, and authorship. It is not intended for analysis. UCI researchers with general analysis questions should sign up for a free BERD drop-in session.

BERD Drop-In Consultations:

The ICTS BERD unit provides free 30-minute consultations for general analysis questions to UCI researchers. Virtual appointments are available on Tuesdays between 12:00pm – 2:00pm. Sign up for an appointment [here](#) (UCInetID login required). If you do not have a UCInetID, please contact Ericka Whitton at ewhitton@hs.uci.edu to book your drop-in appointment.

Effective Collaboration with a Statistician:

Please refer to [this excellent article](#) to learn more about what to expect when collaborating with a statistician.

Scope of Work

Scopes of Work (SOWs) are required for all projects except for those by UCI researchers who are paying via subscription model (see Payment Options below). BERD/CSC statisticians work with principal investigators (PIs) and appropriate research staff to consult on the needs of the project. This consultation should take place during the first free hour (described above).

BERD/CSC statisticians draft the Scope of Work (SOW) which details the expectations of the work to be performed, including:

1. A description of the project
2. Timeline including deadlines
3. Deliverables
4. Estimated hours and cost
5. Authorship (not accepted in lieu of or in exchange for payment)

SOWs are sent to the client via DocuSign and must be completed **within 10 days**.

PLEASE NOTE: SOWs for internal UCI researchers require a financial contact **and** a valid KFS account number for recharge. If you do not have this information, please check with the Principal Investigator.

External clients (both non-profit and for-profit) must complete a UC Sales and Service Agreement (SSA) in addition to the SOW. This contract can be completed concurrently with the SOW but work on the project cannot begin until **both** the SOW and the SSA are fully executed (signed by all parties).

PLEASE NOTE: SOWs for external clients (both non-profit and for-profit) require a financial contact (the person who works with the PI/Researcher to manage funds and authorize payments). This may be the PI/Researcher themselves or another individual.

Types of Assistance

Grant Preparation:

An important function of the BERD/CSC is to help all UCI investigators and co-investigators with grant preparation for research studies. The following policies and guidelines for newgrant preparation 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 50-hour minimum budget allocation for statistical service to be paid via recharge.
2. The BERD/CSC statistician(s) **must 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 **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 has 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 assists UCI researchers with data analyses and preparation of abstracts, papers, and presentations. The following policies and guidelines apply:

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 two 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/recharge 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. Please note

that we **do not** offer assistance with course work or qualifying exams.

Data Privacy Policy:

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 to the [UCI Information Security and Privacy](#) page.

PLEASE NOTE: Hiding columns in Excel or any other database manager does not constitute removal. All columns with PII must be deleted/removed.

Acknowledgment and Authorship Policy:

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

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.

We recommend acknowledging statisticians in publications and presentations if they made significant 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. The consulting statistician reserves the right to decline authorship when offered.

PLEASE NOTE: Authorship is not accepted in lieu of or in exchange for payment.

Deadlines

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. **Please plan to start at least 6 weeks before the due date for assistance** with study design, protocol development and preparation. Data analysis, depending on the complexity, may range from a few hours to many months. 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.

Payment Options

Principal investigators (PIs) can choose from the following service models:

UCI Researchers:

1. **Recharge Model (hourly rate):** Rates are currently \$110 per hour (subject to change). UCI researchers must provide a KFS account number for departmental, grant, or other funds. **This internal rate is only available to UCI researchers who are paying via recharge.** UCI researchers whose statistical analyses is being paid for by a non-profit or for-profit entity will be billed the external rate, as appropriate.

KFS Account Numbers and Financial Contacts: A KFS account number (two letters, followed by five numbers) is required for recharge. The financial contact is the person who works with the PI/Researcher to manage funds and authorize payments.

2. **Grant Support Model:** Free when the BERD/CSC statistician is invited to be included at a minimum of 5% effort. When the percent effort is less than 5%, clients will be billed on an hourly basis.

The goal for providing grant support at no cost is to cultivate a collaborative environment that will lead to successful grant applications. For applications that BERD/CSC staff help prepare and write, it is expected that the principal investigator will invite our statisticians 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 chance that the grant will be funded.

3. **Subscription Model:** UCI principal investigators who require statistics support on a variety of projects may “subscribe” to a portion of BERD/CSC staff time. Those requesting this model must agree to fund **a minimum of 10% effort for at least 6 months. This payment model is only available to internal UCI clients.** A Memorandum of Understanding (MOU) detailing the length of agreement, account details, and contact information must be signed by all necessary parties before work may begin.

External Researchers (both Non-Profit and For-Profit):

A **UC Sales and Service Agreement (SSA)** is required before work on the project may begin. This contract is in addition to the Scope of Work (SOW), which can be completed concurrently.

1. **Fee-for-Service Model (Hourly Rate):** Rates are currently \$145 per hour for external non-profits and \$170 per hour for external for-profits.
2. **Grant Support Model (Sub Award Required):** Free when the BERD/CSC statistician is invited to be included for a minimum of 5% effort. When the percent effort is less than 5%, clients will be billed on an hourly basis. If BERD/CSC staff are not invited to be included on the grant for a percent effort, the hourly rate will apply. Please note, this payment model requires the client have a sub award in place for the project.

Prepayments

We do not accept prepayments under any circumstances.

Payments and Invoicing

All clients who are billed on an hourly basis will receive monthly invoices sent to the email

address on file.

UCI researchers paying via departmental recharge are responsible for providing a valid KFS account number that is appropriate for the recharge.

External researchers (both non-profit and for-profit) should make checks payable to “UC Regents” and note the invoice number on the payment.

Statistical Financial Support for UCI Researchers

UCI researchers who do not have funds available from extramural grants should seek funding from departmental sources or ICTS project grants.

Faculty, staff researchers and graduate students in the following schools may qualify for limited free assistance:

1. School of Biological Sciences
2. School of Population and Public Health

ICTS grant recipients qualify for limited free assistance.

For more information, contact BERD/CSC Director, Dr. Joni Ricks-Oddie (jricksod@uci.edu) or CSC Business Manager, Margaret Erel (merel@uci.edu).

Scheduling a Consultation

Please use the following links to schedule a consultation:

BERD: <https://icts.uci.edu/research-resources/berd/request-berd-resources/>

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