GUIDELINES FOR RESEARCH INITIATIVE/PROPOSAL DEVELOPMENT
Biostatistics, Epidemiology and Research Design (BERD)
UC Irvine Institute for Clinical and Translational Science (ICTS)

April 22, 2013 (updated September 9, 2015)

Guidelines

1. **Timeline** – Please contact ICTS BERD at least eight weeks before the deadline.

2. **Research initiative development** – We focus on the scientific and study design aspects of research initiative/proposal development. This may include
   - Designing the specific aims/objectives and hypotheses
   - Selecting appropriate primary and secondary outcome measures
   - Determining study designs to achieve study aims efficiently
   - Determining sample size and power (and associated ethical considerations)
   - Developing analytic plans (matching specific aims)
   - Developing implementation strategies: randomization schemes, blinding etc.
   - Developing analytical/statistical team appropriate for the research

Inappropriate design and/or inadequate statistics are likely to reduce your chance of success on a research proposal/initiative. The above list of BERD services are designed to avoid common flaws, which may include
(a) overall inappropriate study design,
(b) inadequate or even no statistical analysis plan,
(c) inappropriate statistics not matching the specific aims and hypotheses,
(c) no or inadequate power / sample size analysis,
(d) inadequate effort devoted to statistical needs that makes the analytical component of the proposal not credible,
(e) lack of a plan for data management and data quality assurance/control,
(f) lack of appropriate plan for recruitment/retention and
(g) lack of a strategy for alternative approaches (e.g., alternative design and analysis contingency) among others.

3. **Budget** – The study principal investigator (PI) needs to work with the BERD Director to insure appropriate budget allocation for analytical/biostatistics collaboration.

   **Effort:** The biostatistics research personnel time effort will depend on the specific research study proposal. For example, the minimum effort allocation for typical research studies (e.g., R01 proposal) should be about 10% effort. For larger projects, an appropriate level can be determined, which may be 5-20% or more of a senior faculty statistical investigator and 20-100% of one (or more) staff statisticians (depending on the type of study). Biostatistical effort required for successful conduct of a project are nearly always underestimated so the PI must work with the BERD Director to avoid this.

   **Budgeting across years:** Budgeting should be across all years and may be variable year-to-year. Budget with level funding across the project period is an approach that works well in practice because it accommodates statistical inputs on data collection procedures, changes
to the study design, and preliminary analyses among other activities that typically occurs in nearly all studies. Budgeting for statistical support only in the last year typically does not reflect the actual workload. "If statistical consultation is neglected during the earlier study phases, it can result in nearly useless data at the end of the study, due to avoidable problems in study conduct." (UC Davis CTSC)

4. **Biostatistics letters of support** –

   - Funded co-investigators (e.g., faculty biostatistician) on a research proposal are usually **not needed** to provide a letter of support, but we can provide one if needed.
   - A letter of support is **typically needed** when the research project includes a staff statistician from the ICTS BERD Unit. In this case, the ICTS BERD Director, will write a letter of support.
   - **Usually, we will not write a letter of support** if we do not have a defined role in the research project. This is consistent with other components of a research plan, whether using a Core service or getting a letter from an offsite collaborator; you do not ask for a letter if you are not using the Core service or if the individual is not involved in the research project. Getting a letter in these situations are not only inappropriate, it may raise credibility issues regarding your research implementation plan. If statistics is needed or is an integral part of your research project, then the only credible approach is to provide a method for achieving the specific level of support.

5. **Research initiatives involved in training activities** – Currently there are limited institutional support for these activities and we are working to increase capacity to support research proposals related to training activities (e.g., training proposal). Therefore, please contact the BERD Unit early for consultation related to proposal targeting training grants.

**How to Request BERD Services**

   - Please fill out the short application for BERD services at [http://www.icts.uci.edu/services/berd.asp](http://www.icts.uci.edu/services/berd.asp) (click on Apply Now button)

---

**Fee Schedule**

BERD consulting services are offered on a fee-for-service basis generally. [http://www.icts.uci.edu/service-rates.asp](http://www.icts.uci.edu/service-rates.asp)

   - Initial needs-assessment consultation: The first hour is free of charge.
   - UC Irvine investigators (faculty, staff or students): $80 an hour.

*To support junior investigators (e.g., K awards application), additional free BERD consultation hours may be available. Please contact the BERD Unit early on in your projects.*
Acknowledging ICTS Support

To help ensure that the resources described here are available for future research, please cite the ICTS grant. If you have received funding through the ICTS or used any ICTS services to support your research, please use the following citation:

*The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1 TR001414. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.*

Questions?

If you have questions about this guide, please contact the BERD Director, Dr. Danh Nguyen at danhvn1@uci.edu.