**BERD Mission:** Our mission is to contribute to the acceleration of treatment discoveries across the spectrum of human disease/injury by providing exceptional biostatistics collaboration and education.

**Who We Serve:** The UC Irvine ICTS BERD Unit serves the health science research community at UC Irvine as well as other investigators at UCI and community partners engaged in clinical and translational research. We encourage all levels of investigators, from graduate students, residents, and fellows to faculty, to consult with the BERD Unit.

**Services We Provide:** We support researchers on all types of projects, ranging from brief consultation for statistical advice to long-term partnership on large interdisciplinary program projects, multi-center trials, and population-based studies. Specific consultation and collaboration services include:

- Grant proposal preparation
- Leadership on program project statistical & data coordinating cores
- Study design, Statistical analysis plan
- Power and sample size calculation
- Data analysis and interpretation, Statistical advice
- Manuscript/Poster/Abstract review and preparation
- Response to reviewers
- IRB application
- Biostatistics education, Seminars on biostatistics
- Training in the use of statistical software
- Research database design

To maximize scientific excellence, consultation and partnership with the BERD Unit at the early planning stages of your study is critical.

More information: http://www.icts.uci.edu/services/berd.asp

**Collaboration with Research Protections (RP, Office of Research)** In collaboration with the IRB, we provide scientific review of study protocol for biomedical/clinical research involving greater than minimal risk (for non-cancer research that is investigator-authored and has not been subject to full peer review).

http://www.research.uci.edu/compliance/human-research-protections/researchers/scientific-review.html
Data in this report: Beginning in April of 2013, the ICTS BERD unit deployed a project management system using REDCap. This report provides semi-annual and cumulative data on the characteristics of BERD projects, services project, and summary characteristics of investigators who have utilized BERD services and collaboration.

Number and types of projects

- Table 1: Number of Projects
- Table 2: Clinical Trials
- Table 3: Project Type

Characteristics of Investigators

- Table 4: Investigator's Department
- Table 5: Investigator's Position/Title

Detailed BERD services provided

- Table 6: Service Provided

Data on IRB scientific review

- Table 7-1: IRB Scientific Review - First Review Result
- Table 7-2: IRB Scientific Review - Review Time
- Table 7-3: IRB Scientific Review - Total Review Numbers

Data on consultation and collaboration on research grant proposals

- Table 8-1: Grant Application (with %effort) - Agency
- Table 8-2: Grant Application (with %effort) - NIH Grant Type
- Table 9-1: Research Proposal (no %effort) - Agency
- Table 9-2: Research Proposal (no %effort) - NIH Grant Type
How many research projects have we support recently?

• In the past 3 and a half years, BERD contributed to 490 projects
  o About 29% of those are from the weekly drop-in consult service
  o The vast majority, 71%, are from regular projects, including scientific review requests from the IRB – Human Research Protection: http://www.icts.uci.edu/services/berdScientificReview.asp

Table 1: Number of Projects

<table>
<thead>
<tr>
<th>period</th>
<th>2013, Jan-Jun</th>
<th>2013, Jul-Dec</th>
<th>2014, Jan-Jun</th>
<th>2014, Jul-Dec</th>
<th>2015, Jan-Jun</th>
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<th>2016, Jan-Jun</th>
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<td>%</td>
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<td>80</td>
<td>100.0</td>
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</table>

Drop-in projects: BERD offers weekly drop-in consultation at UCIMC and UCI Campus. A drop-in consultation may span several/multiple drop-in sessions, particularly for medical students, residents and fellows.

Regular projects: Are often longer-term project where an investigator requested BERD services through our on-line application process
How many projects are related to clinical trials?

- 23% - about 1 out of every 4 BERD consultations or collaborations involves a clinical trial.

**Table 2: Clinical Trials**

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<th>2016, Jan-Jun</th>
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What types of research projects do we work on?

Data from the past 3 and a half years shows that about

- 22% involve grant proposals (with and without % effort for BERD personnel)
- 29% involve data analysis/research collaboration
- 10% involve helping investigator on writing research/IRB protocol
- 16% are IRB scientific reviews

See Table 3 below for other project types.

Table 3: Project Type

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<td>9 11.1</td>
<td>18 22.5</td>
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<td>7 15.6</td>
<td>11 16.4</td>
<td>2 3.2</td>
<td>66 13.9</td>
</tr>
<tr>
<td>Data Analysis / Research Collaboration</td>
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<td>21 26.3</td>
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<td>45 100.0</td>
<td>67 100.0</td>
<td>62 100.0</td>
<td>474 100.0</td>
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</table>

Other includes curriculum development, data management, and manuscript reviewer.
What department/schools/partners seek BERD collaboration?
Data from the past 3 and a half years shows that

- **83% of investigators are from departments in the School of Medicine**
- **10% are from UCI departments not in the School of Medicine**
- **2% are from Children’s Hospital of Orange County (CHOC) partners**
- **1% are Memorial Care partners**
- **4% are non-UCI affiliated (e.g., community research organization, industry)**

See Table 4 below.

**Table 4: Investigator's Department**

<table>
<thead>
<tr>
<th>Department</th>
<th>2013, Jan-Jun</th>
<th>2013, Jul-Dec</th>
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<th>2015, Jul-Dec</th>
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Who are the people we collaborate with?
Data from the past 3 and a half years shows that BERD services have reached a broad spectrum of UCI population.

- About 53% are faculty (all professor series)
- 22% are students

See Table 5 below.

Table 5: Investigator's Position/Title

<table>
<thead>
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<th></th>
<th>2013, Jan-Jun</th>
<th>2013, Jul-Dec</th>
<th>2014, Jan-Jun</th>
<th>2014, Jul-Dec</th>
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'UCI - Other Academic' includes Researcher, Project Scientist, and Specialist series.
Specifics of the types of BERD services we provide are summarized below.

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**IRB Scientific Review – First SR Outcome**

BERD has requested by Research Protection (IRB) to provided SR on 74 protocols since 2013.

- **About 1 of 2 protocols (50%)** have major deficiencies that requires revision prior to full IRB reviews.

- **We strive to provide constructive feedbacks for investigators** so that their study can be improved and proceed timely IRB review.

- **We provide at no cost BERD services to help investigators with IRB protocols deficiencies.**

- **To avoid conflict of interest, BERD services (scientific and study design) for IRB protocols are also provided at no cost.**

**Table 7-1: IRB Scientific Review - First Review Result**

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<tr>
<th>Period</th>
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<th>2013, Jul-Dec</th>
<th>2014, Jan-Jun</th>
<th>2014, Jul-Dec</th>
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<td>%</td>
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**IRB Scientific Review – Review Time**

The review of each protocol typically takes over 3 hours, although it can take as much as 10 hours.

**Table 7-2: IRB Scientific Review - Review Time**

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### Table 7-3: IRB Scientific Review - Total Review Numbers

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**Grant Application**

*Data from the past 3 and a half years:*

- **We have collaborated with investigators on 40 grant applications, which included BERD personnel as co-investigator or research staff (Table 8-1)***
  
  *The majority of these grants, submitted to NIH, are R01’s. (Table 8-2)*

- **We have assisted investigators on 66 grant applications where, due to the limited BERD involvement or the nature of the grant (e.g. training grants), % effort for BERD personnel were not included on the grant. For these we refer investigators to utilize the BERD fee-for-service mechanism. (Tables 8-3 and 8-4)***

See Tables 8-1 through 8-4 below.

**Table 8-1: Grant Application (with %effort) - Agency**

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