



## Biostatistics, Epidemiology, and Research Design

### Key Component Activity

<http://osctr.ouhsc.edu/biostatisticsepidemiology-core>

## Policies and Procedures

- **Services Provided**
  - A. Research design and analysis
    - Formulate research questions that are well-defined, measurable, and answerable
    - Consult on design and planning of research projects
    - Develop valid and efficient research designs
    - Identify sufficient sample sizes
    - Guide the selection of measurement methods and instruments
    - Develop case report forms, databases, and online data capture tools
    - Process and program data
    - Create data and safety monitoring plans
    - Analyze data and report data findings
    - Create publication-quality summary tables and figures
    - Conduct systematic review and meta-analysis
  - B. Training support
    - Create and offer seminars, short courses and workshops related to biostatistical and epidemiological methods applied to study design and data analysis
    - Participate in clinical or translational working group meetings or journal club sessions
    - Catalog teaching material, including videostreams of seminars and short courses developed and brief tutorials, for asynchronous learning
  - C. Novel methodologies
    - Development of new statistical methodologies or novel application of existing methods to address project aims
    - Implement novel research designs to maximize validity and efficiency
    - Identify promising areas for development of novel methodologies or the use of known methods to a new area of research
    - Provide opportunities for the development and application of these new methods

- Organize short-courses in novel epidemiological or biostatistical approaches to complex problems
  - Organize multidisciplinary discussion panels to stimulate the development of novel approaches to address biomedical questions
  
- **BERD Personnel**
  - Julie Stoner, PhD, Director, Consultative and Collaborative Unit**

    - **Expertise:** design and analysis of clinical trials, systematic review and meta-analysis, analysis of cluster-correlated and longitudinal data
    - **Areas of Interest:** diabetes, cardiovascular disease, oral health
  
  - David Thompson, PhD, Director, Training Unit**

    - **Expertise:** longitudinal data, clinical epidemiology and clinical decision-making
    - **Areas of Interest:** neurology, pediatrics, physical medicine and rehabilitation, physical therapy
  
  - Hélène Carabin, PhD, DVM, Director, Novel Methodologies Unit**

    - **Expertise:** epidemiology of infectious disease, group-randomized trials, analysis of hierarchical data, epidemiologic methods
    - **Areas of Interest:** international health, zoonoses
  
  - Christopher Aston, PhD, Faculty Biostatistician**

    - **Expertise:** statistical methods in the analysis of genetic epidemiology studies, clinical trials
    - **Areas of Interest:** diabetes, genetics
  
  - Tabitha Garwe, PhD, Faculty Epidemiologist**

    - **Expertise:** clinical epidemiological methods, quantitative epidemiological methods
    - **Areas of Interest:** geriatric trauma, injury epidemiology, infectious disease epidemiology
  
  - Toby Hamilton, PhD, OTR/L, FAOTA, Faculty, Qualitative Research Methods**

    - **Expertise:** qualitative research methods, narrative summary
    - **Areas of Interest:** occupational therapy, prisoner successful community reentry
  
  - Courtney Montgomery, PhD, Faculty Genetic and Molecular Epidemiologist**

    - **Expertise:** identification of genetic and environmental causes of complex disease, including the design, implementation and analysis of genetic and genomic data; high-dimension data analysis of biological and clinical systems

- **Areas of Interest:** autoimmune and inflammatory disorders, relationship between environmental triggers and genes specifically with respect to innate and adaptive immunity

**Jennifer Peck, PhD, Faculty Epidemiologist**

- **Expertise:** reproductive and perinatal epidemiology, observational study design and analysis
- **Areas of Interest:** gestational diabetes, pregnancy outcomes, infertility, environmental exposures to endocrine disrupting compounds

**Jonathan Wren, PhD, Faculty Geneticist/Informatics**

- **Expertise:** bioinformatics, genomic analysis, transcriptional analysis (microarray/RNAseq), text mining
- **Areas of Interest:** predicting function, phenotype and disease relevance for uncharacterized genes and non-coding RNAs; knowledge discovery; biomarker identification and prioritization

**Ying Zhang, MD, PhD, Faculty Biostatistician**

- **Expertise:** longitudinal data analysis, multilevel modeling, quantitative epidemiological methods
- **Areas of Interest:** epidemiology and prevention of cardiovascular diseases and diabetes, genetic epidemiology of chronic disease with an emphasis on cardiovascular diseases, diabetes, and obesity

**Daniel Zhao, PhD, Faculty Biostatistician**

- **Expertise:** clinical trials, animal studies
- **Areas of Interest:** oncology, rheumatology, diabetes, basic science

Staff

**Pravina Kota, MS, MBA, Senior Systems Analyst**

- **Expertise:** database development, programming, data reporting, public health program evaluation
- **Areas of Interest:**

**Ji Li, MS, Research Biostatistician**

- **Expertise:** analysis of longitudinal data, survival data analysis, and structural equation modeling
- **Areas of Interest:** oral health, behavioral science, influenza

**Lindsay Boeckman, MS, Research Biostatistician**

- **Expertise:** SAS programming and automated report generation, public health program evaluation, database integration
- **Areas of Interest:** oral health, tobacco cessation and control

**Thomas Wilson, MPH, Sponsored Program Coordinator**

- **Expertise:** REDCap database administration and programming
- **Areas of Interest:** pediatrics

**Sydney Martinez, MPH, Research Project Coordinator and Evaluator**

- **Expertise:** evaluation, survey development and data analysis, qualitative data analysis
- **Areas of Interest:** tobacco control, physical activity and nutrition, health disparities, community-based prevention programs

Student Graduate Research Assistants

**Xi Chen, MD**

## **CONSULTATIVE AND COLLABORATIVE UNIT**

- **Support Requests**
  - A. Research project support request
  - B. Training support request
  - C. Novel methodologies request

- **Project Prioritization**

Projects are prioritized according to the following priority rankings:

1. OSCTR Pilot Grant Recipients
2. OSCTR Scholars
3. OSCTR TPIR Trainees
4. NIH-defined New or Early Stage Investigators
5. Projects involving two or more OSCTR partners
6. NIH-funded investigators
7. Senior non-NIH funded investigators
8. Industry trials

- **Funding Guidelines**

- A. For grant applications that include BERD personnel, salary support will be included when allowable under the funding mechanism. The minimum percent effort funded on a grant is generally 10% FTE of a faculty or staff member for

clinical studies and 5% FTE for basic science studies. Additional support for programmer/analyst or project coordinator time may be required. When faculty salary is not allowed under the funding mechanism, in-kind contributed effort must be approved by Dr. Stoner if the time is supported through the FTE that is funded by the OSCTR BERD budget. In addition, when faculty time is not allowed under the funding mechanism, design and data analysis support by staff will be requested in the grant budget. For one- to two-year pilot projects, \$2,000-\$5,000 per year is typically requested for BERD staff support.

- B. Supplemental funds will be requested if an investigator or group requires more than 10% FTE of dedicated time from a given faculty, staff, or graduate research assistant member of the BERD. A Memorandum of Understanding with the investigator or group will be developed to cover the salary and fringe of the BERD member, as well as a 3% computer/server overhead charge. Typically, such funds will offset additional salary of the BERD member without requiring a reduction in the BERD funding for that member.
  - C. Graduate research assistant time for data entry is limited to 20 hours of support funded by the BERD for a given project. Effort beyond the initial 20 hours will be funded through supplemental arrangements to cover the salary and fringe of the student.
- **Timelines**
    - A. Submitted requests are reviewed and an initial email response is sent to the investigator and assigned BERD personnel member within two working days of the submission.
    - B. Within two working days of receiving the request, the BERD member will contact the investigator to schedule a meeting to discuss the project.
    - C. With rare exception, we require grant proposals to be submitted to the BERD for support at least three weeks before the grant submission deadline.
    - D. Timelines for data cleaning and analysis are as follows:
      - We require a minimum of two weeks for data cleaning and data processing. This process will involve generating a listing of data queries to be addressed by the investigator before statistical analyses are performed.
      - We require a minimum of two weeks for descriptive and univariate analyses after the data have been cleaned and queries have been addressed.
      - We require a minimum of four weeks for multivariate analyses or analyses involving weighted, hierarchical sampling, or longitudinal data after the data have been cleaned and queries have been addressed.
- **Planning and Communication of Expectations**
    - A. Co-authorship
      - BERD personnel are expected to be co-authors and the decision on authorship should be based on scientific contribution, independent of

funding consideration, as per the International Committee of Medical Journal Editors guidelines

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

#### B. Initial Consultation

- Investigators should prepare responses to the following questions for initial consultation visits:
  - Statement of research questions:
    - Primary objectives, which in turn will eventually determine:
      - Research design
      - Data measurement methods and protocol
      - Choice of statistical strategy
      - Calculations of sample size, effect size, or statistical power
    - Secondary objectives
  - Details regarding primary research question:
    - Outcome of interest
    - Level of measurement (nominal, ordinal, interval, ratio) to focus and limit the realm of useful statistical tools, models, or approaches
    - Assessment of measurement error and misclassification
  - Design issues related to primary question:
    - Comparison groups, based on intervention, based on interest in stratification by important cofactors, covariates, or confounders
    - Hierarchies, clusters, or correlations among the outcome measures such as repeated measures over time (i.e., measures taken each week), spatially correlated data (i.e., measures from left and right eye), natural groupings (i.e., families, clinics, etc.).
  - Plans to measure continuous or categorical covariates that will permit:
    - Exploration of subgroup associations (statistical interaction or effect modification)
    - Adjustment for confounding of the primary association of interest by factors known or suspected to be associated with the outcome from previous literature
    - Assessment of measurement error and misclassification
  - Preliminary data or published papers that provide estimates of:
    - The magnitude of the outcome of interest (such as group means or proportions)
    - The magnitude of the variability you expect in your outcome (usually standard deviation)

- These will be used to calculate sample size, effect size, and power
- Details regarding the participants in your study
  - Inclusion criteria to help define the population(s) of interest from which group(s) will be selected or sampled
  - Exclusion criteria that, by restricting the sample, limit the influence of potential confounding variables or known sources of variation
- Sampling plans (random, stratified, paired)
- Requirements associated with delivery or sharing of study data
  - Data must be de-identified so that it has no direct identifiers such as:
    - Name
    - Street name or street address or post office box (i.e., not including city, state, or ZIP code)
    - Telephone and fax numbers
    - Email address
    - Social security number
    - Certificate / license numbers
    - Vehicle identifiers and serial numbers
    - URLs and IP addresses
    - Full-face photos and other comparable images
    - Medical record numbers, health plan beneficiary numbers, and other account numbers
    - Device identifiers and serial numbers
    - Biometric identifiers, including finger and voice prints

### C. Delivery of Data

- The study protocol and IRB approval must accompany data.
- A data dictionary should accompany data and should include:
  - Variable names
  - Units of measurement for each continuous variable
  - Definitions for levels of categorical variables with underlying continuous measures
  - Definitions of codes for nominal categorical variables like race, ethnicity, county, etc.
- If data is not de-identified then send via the following link: <https://securefiletransfer.ouhsc.edu/> . You will need to Zip the file(s) to send via the link.

Visit the following link for more information and directions:

<http://it.ouhsc.edu/services/SecureFileTransfer.asp> .

#### D. Referral Outside BERD

Project requests submitted to the BERD that require research methodological expertise that is not available among the BERD members will be considered on a case-by-case basis. If the project is of high priority, the BERD KCA leader will assist the investigator in identifying research methodologists with relevant expertise to address the needs of the project. In addition, BERD funding may be available to support the salary and fringe of the identified methodologist. To be considered for funding, and in order to determine the appropriate FTE and funding period for the methodologist, investigators must submit a project request form through the REDCap system that includes a summary of the aims of the project, a brief summary of the study design, an analytic plan (if available), a summary of the research methodological skills that are needed, and an overall timeline for completing the work.

#### E. Development of Scope of Work, Timeline, and Deliverables

At the initial consultation meeting, BERD members will develop, and communicate with the project investigator within two weeks of the initial meeting, a project timeline, a summary of the scope of work, and a listing of deliverables related to the project. Project planning and report templates are available for BERD member use to standardize communications with investigators.

- **Documentation of Work and Products**

Investigators requesting support through the BERD will submit a project request form available at <https://redcap.ouhsc.edu/redcap/surveys/?s=u8Tipfbiwk>. This request form will include investigator and project information that will populate fields of the BERD Time and Accomplishment tracking database that will be used by BERD personnel to record project work and product information.

BERD members should regularly update the Access BERD Time and Accomplishment database to reflect their project work time as well as project accomplishments including abstract and manuscript submissions and publications, grant submissions and awards, and presentations.



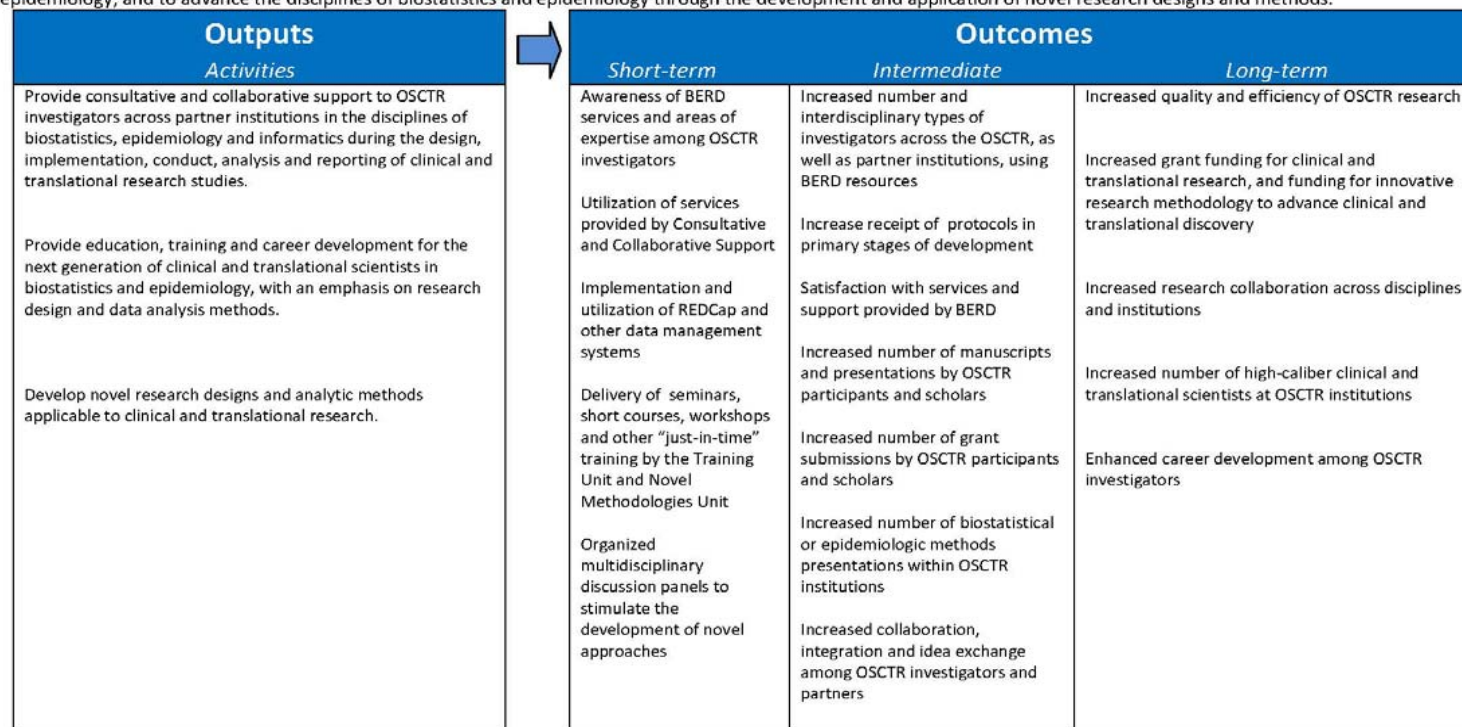
- Program Evaluation

The BERD program evaluation is guided by the following Logic Model.



### BERD KCA Logic Model

Goals: To enhance the quality and productivity of research conducted by OSCTR investigators by providing consultative and collaborative support in the disciplines of biostatistics, epidemiology and informatics; to provide training and career development for clinical and translational researchers in the disciplines of biostatistics and epidemiology; and to advance the disciplines of biostatistics and epidemiology through the development and application of novel research designs and methods.



**Assumptions**  
By building upon the existing efforts of the OUHSC Department of Biostatistics and Epidemiology and OMRF to organize the combined biostatistics, epidemiology and informatics resources in the OSCTR and provide an umbrella organization to bring together a diversity of campus resources into a single entity, we will greatly facilitate the quality of research, as well as the productivity and translation of research findings into practices within the community.

**External Factors**  
Funding; competing priorities for clinical investigators; potential lack of subject matter experts; sufficient technical support and infrastructure for training needs; transition/adoption/integration of electronic health records; other institutional barriers

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Evaluation approaches include:

- A. Investigator satisfaction surveys
- B. Tracking of projects and products to quantify measures associated with the short-term, intermediate, and long-term outcomes.