Process for Biostatistics and Research Design Shared Resources (BRD SR) Access and Project Tracking

Scientific Director: Sara Vesely, PhD

Summary:
Stephenson Cancer Center (SCC) investigators requesting biostatistical support will complete an online project intake form that is available through the SCC Biostatistics and Research Design Shared Resources (BRD SR) web page. All subsequent work and products, including manuscripts, grant applications, abstracts and analysis reports, will be tracked by the BRD SR members using a project tracking database. Reports summarizing personnel time and project products will be generated quarterly and discussed with SCC administrators.

Forms and Databases:

1. Project intake form
    a. Purpose:
        - Used by investigators to request biostatistics support
        - To record basic information regarding project design, specific aims, and support requested
    b. Structure/Process:
        - Biostatistics and Research Design Shared Resources (BRD SR) staff will develop the online project intake form and related SR posted on the website. All web content will be reviewed by Wade Williams, PhD before posting.
        - Online project intake form
        - Hosted on Stephenson Cancer Center site: https://www.ouhealth.com/stephenson-cancer-center/cancer-research/cancer-shared-resources-services/biostatistics-research-design/
        - Following the submission of the intake form, an email is sent to the BRD SR faculty that includes the project information. BRD SR staff will also review the PI information to ensure that the PI is an SCC member. If the PI is not an SCC member, BRD SR staff will invite them to apply for membership and will notify Dr. Vesely to hold the project until membership is approved.
        - Dr. Vesely will review the project information and determine whether the project relates to the mission of the SCC. If there are concerns regarding the relevance to cancer research, Dr. Vesely will forward the request to the indicated Research Program director to determine whether the project is relevant and should be supported through the SCC BRD SR.
        - Information recorded on the intake form will be directly entered into a RedCap database
        - Sara Vesely will have primary responsibility for checking the SCC_biostat@ouhsc.edu email account and will distribute projects

among the BRD SR faculty based on area of expertise, primary research program affiliation, and available time.
    - All projects must be submitted through this portal to ensure accurate accounting of time and project work.

c. Functions:
    - Generate report summarizing number and characteristics of requests over a certain period

d. Process:
    - Project requests will be reviewed by a BRD SR member and an initial email response will be sent within 2 working days

Policies: Guidelines for investigators

The biostatistics core provides statistical consultation and collaboration on protocol and grant development, manuscript preparation, and other scholarly activities that need statistical insights.

Part A. Project Prioritization

Projects will be prioritized according to the following criteria:

- *Member status of the user*: CCSG funds will only be used to support full members with peer-reviewed support. Associate members, affiliate, clinical and non-SCC members (conducting cancer-related research) will be prioritized in this order using funds from other sources.
- *Type of project*: 1) NIH/NCI Center or multi PI projects (P Awards, U Awards); 2) investigator-initiated studies; 3) NCI-funded projects; 4) other peer-reviewed funded projects; 5) non peer-reviewed funded projects; and 6) unfunded projects.

Part B. Grant Preparation

With rare exception we require grant proposals involve biostatisticians at least three weeks before submission. The BSE faculty will include salary support on grant applications. Funding support for salaries of BSE faculty that is obtained through successful grant applications will permit a redistribution of the above expenditures, which will in turn support effort from additional BSE staff and faculty. Grants that aim to provide research infrastructure, including U-awards, center grants, or COBRE grants, may offset the listed expenditures while other grants that are focused on a specific research project, including R01 grants, will not offset the listed expenditures, but will instead add to the funding for biostatistical support.

The minimum percent effort funded on a grant is generally 10% for clinical studies and 5% for basic science studies for faculty biostatisticians. For grants that prohibit funding faculty time, Biostatistics Core staff or graduate research assistant time should be funded through the project budget to supplement in-kind faculty time that is contributed to the project. Effort contributed in kind without grant salary support will be funded through the Stephenson Cancer Center BRD SR funding and must be approved by Dr. Robert Mannel.

Part C: Manuscript and Abstract Preparation

We require a minimum of two weeks (for simple analysis) and four weeks (for complex analyses) to deliver initial statistical analysis results for abstracts and manuscripts.

Biostatisticians 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/icmje-recommendations.pdf).
https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-authorship_contributions.pdf

Authorship Guidelines can be found here
https://www.ouhealth.com/documents/content/cancer/AuthorshipGuidelines-final.pdf

Part D: Initial Consultation Visits

Investigators should prepare for the following questions for initial consultation visits.

1. Statement of research questions, linked directly to

a. Primary objectives, which in turn will eventually determine
   i. choice of statistical strategy
   ii. calculations of sample size, effect size, or statistical power
b. Secondary objectives

2. Details regarding primary research question

a. Outcome of interest
   i. Level of measurement (nominal, ordinal, interval, ratio)
   The outcome's level of measurement focuses and limits the realm of useful statistical tools, models, or approaches.
b. Design issues related to primary question:
   i. Comparison groups
   - Groups based on intervention
   - Groups based on interest in stratification by important cofactors, covariates, or confounders.

c. Participants
   i. inclusion criteria that help define the population(s) of interest from which group(s) will be selected or sampled
   ii. exclusion criteria that, by restricting the sample, limit the influence of potential confounding variables or known sources of variation

3. Other design issues

a. Sampling plans (random, stratified, paired)

b. Plans to measure continuous or categorical covariates that will permit:

i. exploration of subgroup associations (statistical interaction or effect modification)

ii. adjustment for confounding of the primary association of interest:

- by factors known to be associated with outcome
- by factors suspected to be associated with outcome

c. Hierarchies, clusters or correlations among observed outcomes

Repeated measures over time

Natural groupings, including families, classrooms, clinics

d. Sample size, effect size, and power

Preliminary data or published papers that provide estimates of the outcome's magnitude (group means and proportions) and variability (standard deviations).

4. Requirements associated with delivery or sharing of study data

a. Data must be deidentified
b. Study protocol must accompany data
c. 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.