Course Objectives: This course is intended to integrate and apply biostatistical and epidemiologic methods presented in other OJ/OC courses to clinical research data. Students will:

- identify the scientific objectives of a clinical research study and develop a statistical analysis strategy appropriate for those objectives;
- plan strategies for statistical design and analysis and implement these strategies;
- learn to be aware of problems that arise in data collection;
- learn to communicate through presentation of oral and written reports and through student and faculty critiques of these reports;
- learn to communicate results of clinical research projects in clear, accurate, concise language;
- learn appropriate writing styles and formats for clinical research articles, and apply writing skills to research papers.

Students are expected to make 3 presentations, and turn in a written report for each:

Choose any two of #1-3 below (oral presentation plus 1-3 pages written) AND #4:

1) Present the Preliminary Results section for your grant proposal: The written report will include a description of the problem, objectives, hypotheses, and your draft version of the preliminary data section from your grant proposal. The presentation will be a summary of this material. Emphasis is on data presentation. Consider optimal use of graphics and tables. Turn in the PowerPoint slides (“handout” 6/page format) with your written report.

2) Present the Sample Size Justification and Data Analysis sections for your grant proposal: The presentation will show the statistical justification for the sample size planned for your grant proposal. Address the sample size for each relevant Specific Aim separately. The Data Analysis Plan for each Specific Aim will then be described. Address data management and security as well as statistical procedures. Turn in the PowerPoint slides (“handout” 6/page format) as well as the grant proposal sections.

3) Statistical article: Present an article on a statistical topic from the statistical or medical literature. At least a week prior to presentation, post a pdf of the paper on the Ctools website. The presentation and written report should include a summary of the article (50-60% of report), followed by a critique (40-50% of report). Turn in both the PowerPoint slides (“handout” 6/page format) and a 1-2 page written report.

4) Draft manuscript: In this project, you will draft a manuscript, based on analysis of a data set (e.g., your data, data obtained from others (with relevant permission), or public use data). Oral presentation: The manuscript itself will be shown in the presentation -- NOT Powerpoint slides. Written draft manuscript. Emphasis is on the statistical aspects (Methods and Results sections). Reports are to be 1.5-spaced and should be at least 6-8 pages of text, tables and figures, with supporting output in appendices if needed. The written report should use language appropriate for a medical journal and should include the following:

a) Title, author(s), affiliation(s), date.
b) Abstract (half page): A summary of the main findings. Structured abstract preferred.
c) Introduction: A short description of the problem (1-2 paragraphs)

d) Methods: A description of the population, recruitment, eligibility, randomization (if applicable), sample processing methods, etc.

e) Statistical Methods: Describe all data analysis methods used in the paper. A listing of SAS commands for the major analyses could be included as an Appendix.

f) Results: Summary statistics, description and interpretation of the fitted models and parameters estimated, hypotheses tested, confidence intervals, p-values and tabular and graphical representation of the results. Tables and graphs should be clearly labeled.

g) Discussion/Conclusions (2 to 4 paragraphs): Descriptions of the scientific conclusions that can be drawn from the analysis results, implications, discussion of relevant literature, and limitations. It should cover all the main points, but can be in rough form (e.g., bullet points).

**All oral presentations** (including questions and discussion): 15-17 minutes. Focus on statistical content. At least 2/3 of content should be on statistical methods, analysis, or interpretation.

Students are expected to participate actively in classroom discussions. For presentations of published articles (item (3) above), all students are expected to review the papers (posted on Ctools) before they are presented in class.

**Grades:**

The final grade will be determined by the quality of the oral and written reports and by participation of the student in classroom and online discussions. Both technical content and the presentation of that content are important (e.g., organization and clarity of language). Each of the three projects (30%); class participation (10%)

**SPH Policy Statement on Academic Integrity**

The faculty of the School of Public Health believes that the conduct of a student registered or taking courses in the School should be consistent with that of a professional person. Courtesy, honesty, and respect should be shown by students toward faculty members, guest lecturers, administrative support staff, and fellow students. Similarly, students should expect faculty to treat them fairly, showing respect for their ideas and opinions and striving to help them achieve maximum benefits from their experience in the School.

Student academic misconduct refers to behavior that may include plagiarism, cheating, fabrication, falsification of records or official documents, intentional misuse of equipment or materials (including library materials), and aiding and abetting the perpetration of such acts. The preparation of reports, papers, and examinations, assigned on an individual basis, must represent each student’s own effort. Reference sources should be indicated clearly. The use of assistance from other students or aids of any kind during a written examination, except when the use of aids such as electronic devices, books or notes has been approved by an instructor, is a violation of the standard of academic conduct.

**Biostatistics Core Competencies addressed in this course:**

Apply descriptive techniques commonly used to summarize public health data.
Apply common statistical methods for inference.
Apply descriptive and inferential methodologies according to the type of study design for answering a particular research question.
Interpret results of statistical analyses found in public health studies.
Develop written and oral presentations based on statistical analyses for both public health professionals and educated lay audiences.