**SYLLABUS**

*SUNY Downstate Principles of Research Methodology*

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Lecture Hall 4, BSB
5 PM – 6 PM

Faculty
John M. Allen, BS, Assistant Vice President, Office of Scientific Affairs
Jeffrey S. Borer, MD, Professor and Chairman, Department of Medicine
Joseph A. Franciosa, MD, Adjunct Professor of Medicine
Phyllis G. Supino, EdD, Professor of Medicine
Jeremy Weedon, PhD, Associate Director, Scientific Computing Center

This course is intended for physicians, medical students and other members of the Downstate Medical Center (DMC) academic community who are designing research projects, writing grant proposals, or conducting research for publication as a journal article or presentation at a medical society meeting. Its purpose is to familiarize participants with the: (1) principles of problem definition and hypothesis construction; (2) logic of research design and statistics; (3) rationale and procedures for generating and documenting data; (4) fundamentals of writing a protocol or other research proposal; and (5) guidelines for assembling and interpreting results, evaluating and writing scientific papers, and publishing studies. The course consists of 18 one-hour sessions, offered approximately once a week. Its faculty includes senior members of the DMC Department of Medicine, Scientific Computing Center and Office of Scientific Affairs and Biotechnology.

(1) **Identifying and Developing a Research Problem**

(10/5/11  Dr. Supino)
Overview of the research process; importance of the research plan; identifying and refining the problem; characteristics of good research problems; role of the literature review.

(2) **Constructing the Research Hypothesis, Part 1: Role of Research Hypothesis**

(10/12/11  Dr. Supino)
The role of the hypothesis in a research investigation; relation to the research question; logical underpinnings; hypothesis testing vs. hypothesis generating studies (important distinctions); characteristics of well-defined hypotheses; types of hypotheses

(3) **Constructing the Research Hypothesis, Part 2: Developing the Hypothesis**

(10/19/11  Dr. Supino)
Identifying and labeling variables in a hypothesis (independent, dependent, control, moderator; intervening); methodology for developing testable hypotheses (role of the operational definition; operationalizing the hypothesis); real case examples
(4) **Introduction to Case-Control Studies**  
(10/26/11) Dr. Weedon  
Introduction to the methodology of the case control study; selection of cases; selection of controls; case/control ratio; estimation of effect size; statistical testing; confounding; sources of bias

(5) **To Match or Not To Match**  
(11/2/11) Dr. Weedon  
The purpose of matching; frequency vs. one-to-one or one-to-many matching; whether to match; statistical considerations for matched studies

(6) **Cohort Studies: Pros and Cons vs. Other Observational Designs**  
(11/9/11) Dr. Weedon  
The nature and purpose of cohort and cross-sectional studies; estimation of effect size; statistical testing; nested case control studies; relative strengths and weaknesses of these approaches relative to one another and to case-control methods

(7) **Sources of Bias in Studies of Intervention (Pre-Experimental Design)**  
(11/16/11) Dr. Supino  
Distinctions between internal and external validity of a study; common threats to validity (selection, history, maturation, regression, experimental mortality and other sources of bias); examples of pre-experimental designs found in the literature; ethical implications.

(8) **Control of Bias in Studies of Intervention (True-Experimental Design)**  
(11/30/11) Dr. Supino  
Controlling internal and external bias in a study; the concept of blinding in an experimental design; advantages/disadvantages of 4 common alternative true experimental designs (pretest only, pretest-posttest, factorial, and cross-over parallel group designs); examples from the literature; strengths and limitations of controlled clinical trials.

(9) **Control of Bias in Studies of Intervention (Quasi-Experimental Design)**  
(12/7/11) Dr. Supino  
Limitations of randomized designs; practical alternatives for determining intervention effects (“quasi-experimental designs); time series and equivalent time samples designs in preclinical research, the “N-of-1” study in the clinical setting, the non-equivalent control group design; literature examples.

(10) **Data Collection, Preparation and Documentation**  
(12/14/11) Dr. Franciosa  
Sources of data available to answer research questions: retrospective sources (medical chart, vital records, etc.); prospective sources (interviews, questionnaires); ethical/regulatory issues
(11) Estimation, Confidence Limits, and Hypothesis Testing  
(12/21/11 Dr. Weedon)
Relation of the sample to the population; point estimates (proportions and means); the confidence interval (CI): interpretation of CI using probability concepts, construction (upper and lower limits), relation of sample size and degree of confidence to CI width.

(12) Evaluating Differences between Means and Proportions  
(1/4/12 Dr. Weedon)
Understanding/choosing between tests of hypotheses about differences between means (the one sample, two sample, and paired t-test; analysis of variance [ANOVA], nonparametric analogues) and proportions (the chi-square, Fisher’s exact and McNemar’s tests); assumptions, limitations, real case examples.

(13) Correlation and Regression  
(1/11/12 Dr. Weedon)
Testing hypotheses about correlation and linear regression; assumptions; limitations; real case examples.

(14) Statistical Issues in Diagnostic Testing and Screening  
(1/18/12 Dr. Weedon)
Sensitivity, specificity, positive and negative predictive values; ROC curves; biases in assessing diagnostic tests

(15) Advanced Topics in Statistics: Survival Analysis and Logistic Regression  
(1/25/12 Dr. Weedon)
Understanding censored data; how to construct, compare and interpret Kaplan-Meier Product Limit (“survival”) curves; Cox regression, logistic regression (time permitting)

(16) Writing the Research Protocol  
(2/1/12 Dr. Franciosa)
Purpose of the institutional research protocol; ethical underpinnings; format of the introduction and methods sections; human subjects issues (e.g., informed consent, risk/benefit, protection of privacy)

(17) Funding the Research Study  
(2/8/12 Mr. Allen)
Identifying sources of grant funding (e.g., governmental sources, private foundations); format of the grant proposal (institutional data, the research plan, developing the budget); highlighting the significance of the proposed project; submitting the proposal; the review process

(18) How to Prepare, Present, and Publish a Scientific Paper  
(2/15/12 Dr. Borer)
The role of the scientific paper in the research process; general characteristics of scientific writing; organization of the scientific paper (IMRAD format); how to: prepare a title, list authors, write the IMRAD sections, cite references, prepare tables, figures, and illustrations; general linguistic requirements; how/where
to submit a manuscript; the review process; ethical principles.