UKCSRT Curriculum

Begins week of June 22, 2015

**FOUNDATION COURSES IN CLINICAL RESEARCH (50 lectures)**

**Unit 101: Medical Statistics**
This course provides a thorough introduction to the most commonly used biostatistics techniques for clinical research. Specific topics include: tools for describing central tendency and variability in data; methods for performing inference on population means and proportions via sample data; statistical hypothesis testing and its application to group comparisons; issues of power and sample size in study designs; and random sample and other study types. There is an introduction to simple linear regression, multiple linear regression, logistical regression, and survival analysis. The ability to import data into a statistical package from a database or Excel spreadsheet is considered essential in clinical research. Introductory lectures consist of teaching the basic functions of the Stata program, including key commands, do files, getting data into the shape needed for analysis, and checking for errors.

- Lecture 1: Introduction to Medical Statistics
- Lecture 2: Confidence intervals for estimates
- Lecture 3: Hypothesis Testing
- Lecture 4: Power/Sample Size for One-sample, Two-sample Tests
- Lecture 5: Nonparametrics
- Lecture 6: Analysis of Proportions
- Lecture 7: Simple Linear Regression
- Lecture 8: Multiple Linear Regression
- Lecture 9: Logistic Regression
- Lecture 10: Survival Analysis
- Lecture 11: Introduction to Computing for Biostatistics
- Lecture 12: Getting Started with Stata
- Lecture 13: Using Stata Effectively

**Unit 102: Clinical Epidemiology**
This introductory course presents an overview of the basic methods of epidemiology and their applications to clinical research. Lectures explore such basic principles of epidemiology as the importance of measurement (types of outcome measures and measures of association), the diverse array of study designs available in clinical research (cross-sectional studies, cohort studies, case-control studies and experimental designs), and the types of potential biases (selection bias and measurement bias). Confounding and methods for its avoidance and control, effect modification, test evaluation, and the development and evaluation of prediction rules are also covered.

- Lecture 1: Introduction and Outcome Measures
- Lecture 2: Measures of Association
- Lecture 3: Study Design: Randomized Controlled Trials
- Lecture 4: Study Design: Cohort Studies
Lecture 5: Study Design: Case-Control Studies
Lecture 6: Threats to Validity: Bias and Confounding
Lecture 7: Regression in Epidemiology
Lecture 8: Matching and Effect Modification

**Unit 103: Research Ethics**
This course reviews some common challenges in the conduct and review of biomedical human-subjects research. Lectures examine the history and evolution of ethical codes and regulations; the role and responsibility of physicians as investigators with a focus on physician investigators in the UK; the preparation of research protocol applications and informed consent documents; and the challenges of conducting research involving children and adolescents.

Lecture 1: Overview of Ethics
Lecture 2: Key Elements of the Consent Form
Lecture 3: Equipoise
Lecture 4: Special Situations

**Unit 104: Clinical Trials**
This course focuses on how to conduct clinical trials effectively. The course content includes lectures on study design and implementation, including different designs, endpoints, study protocol, study population, recruitment, baseline assessment, randomization, stratification, and blinding. Other key issues that are covered include data analysis and sample size and power, treatment regimens and follow-up procedures, and monitoring and interim analysis plans. Lastly, other areas covered include data management and ethical issues, including protection of human subjects.

Lecture 1: Clinical Trials: Introduction
Lecture 2: Study Design and Ethical Considerations
Lecture 3: Elements of a Study Protocol and Study Endpoints
Lecture 4: Study Population, Recruitment, and Baseline Assessment
Lecture 5: Randomization, Stratification, and Blinding
Lecture 6: Data Analysis Plan, Sample Size, and Power
Lecture 7: Treatment Regimens and Follow-up Procedures
Lecture 8: Monitoring and Interim Analysis Plans
Lecture 9: Miscellaneous Protocol Issues and Study Close-out
Lecture 10: Case Study

**Unit 105: Applied Regression**
The course is designed for students who have completed Unit 101, i.e., students with a good working knowledge of elementary descriptive statistics; sampling distributions; one- and two-sample tests for means and proportions; correlation and basic linear and multiple regression model building. Initially, lectures explore general concepts in linear regression and consider residual analysis and data transformations. Lectures address multiple linear regression, including consideration of confounding and effect modification. Model building is emphasized. Lastly, several lectures explore topics in logistical regression, including 2x2 Tables and stratification, model building and assessment of goodness of fit, and smoothing and generalized additive models.

Lecture 1: Linear Regression: General Concepts
Lecture 2: Linear Regression: Residual Analysis and Data Transformations
Lecture 3: Linear Regression (Part III): Multiple Linear Regression, Confounding and Effect Modification
Lecture 4: Linear Regression (Part IV): Case Study: Circulatory Arrest Study
Lecture 5: Linear Regression (Part V): Model Building
Unit 106: Key Elements of Research Proposals, Posters, and Manuscripts
This course is designed to develop skills in writing research proposals and manuscripts as well as communicating information effectively in poster and oral presentations. How to write each section of a research proposal, the unwritten rules of earning top scores in grant submissions, as well as how to publish papers in high impact journals are also covered. Faculty members have a highly successful track record of funding and have been published in or have edited high impact journals.

Lecture 1: Overview of Proposal and Manuscript Writing
Lecture 2: Key to Writing a Winning Grant Proposal
Lecture 3: Key Aspects of Writing Papers
Lecture 4: The Peer Review Process and Handling Reviewers
Lecture 5: Problem Solving in Manuscripts

Electives (Choose one of either Elective A or B.)

Electives will be available the week of November 2, 2015.

Elective A: Genetic Epidemiology

Lecture 1: Overview of Genetic Epidemiologic Research Study Designs
Lecture 2: Design, Conduct and Analysis of Genetic Epidemiologic Studies and Interpretation of Findings
Lecture 3: How to Evaluate Interactions Among Genes, Environmental Factors, Behaviors, and Their Roles in Health and Disease
Lecture 4: Statistical Analysis of Genetic Epidemiologic Data
Lecture 5: The Legal, Ethical and Social Issues Associated with the Collection and Application of Genetic and Genomic Information
Lecture 6: Technological Aspects of How to Investigate the Role of Genes in Disease and Normal Variation of Traits
Lecture 7: Case Studies in the Genetic Origins of Disease

Elective B: Introduction to Evidence-based Medicine (EBM)

Lecture 1: Introduction to EBM
Lecture 2: Guideline Development
Lecture 3: Meta-analysis and Systematic Review
Lecture 4: Cost Effectiveness Analysis
Lecture 5: Use of Databases to Analyze Evidence
Lecture 6: Statistical Methods for Evaluating Medical Diagnostic Tests
Lecture 7: The Use of Screening Results to Support Clinical Decision Making