Master's Degree Requirements

1) Admissions

a) Eligibility requirements: Candidates must meet the following minimum requirements:
   - Completion of a Ph.D or a professional degree in the health sciences (e.g. MD, DDS, DMD, OD, ND, DO, PharmD, DVM, DNS, etc.) is required. Applications from students currently enrolled in professional or academic degree programs who demonstrate an interest in translational research (pre-clinical, clinical, or community-based) will be considered on an individual basis.
   - Candidates should have a high level of interest and potential to pursue innovative translational research (ranging from pre-clinical to clinical to community-based), and a long-term goal of pursuing a translational research career.
   - Candidates must be current or former scholars in one of the seven clinical/translational mentored research training programs administered by the UCD Clinical and Translational Science Center (i.e. Mentored Clinical Research Training Program, CTSC T32 Predoctoral Program, HHMI Integrating Medicine Into Basic Science Program, CIRM Stem Cell Training Program, BIRCWH K12 program, CTSC K12 Program, Primary Care Outcomes Research Program).
   - Medical students or students in other professional degree programs interested in the one-year option must take a temporary educational leave from their professional degree program for at least one year to pursue the Clinical Research degree program full-time.

b) Application process:
   - Consideration for program admission requires completion of an Office of Graduate Studies online application by the stated admission deadline.
   - Application fees must be paid in full by the admission deadline.
   - Applications must include a 2-4 page research proposal, a description of career development goals, a curriculum vitae, and a description of the mentoring plan with identified mentor(s).
   - In addition to the mentoring plan, letters of support from the prospective mentor(s) will be required of all applicants.
   - For faculty applicants, a letter from the Department Chair (or Division Chief) must be included, and must confirm his/her commitment of release time sufficient to pursue this degree program.

2) M.A.S. Plan II (Plan I is not offered)

M.A.S. Plan II requires 40 units of graduate and upper division courses, as indicated below, of which at least 18 units must be graduate courses in the major field. Not more than 9 units of research (299 or equivalent) may be used to satisfy the 18-unit requirement. Each candidate must complete a final capstone requirement (described in #8). No thesis is required.
3) **Course Requirements:** 31 units of core coursework, 6 units of electives, and at least 3 units of research (299) are required for a total of 40 units as follows:

**a) Required Core Courses (27 units):**
- Clinical Epidemiology and Study Design  CLH 202  3 units
- Introduction to Clinical Research   CLH 200  3 units
- Strategies for Grant Writing    CLH 201  2 units
- Methods in Clinical Research  CLH 203  4 units
- Responsible Conduct of Research  CLH 204  3 units (1 unit/qtr for F/W/Sp)
- Introduction to Medical Statistics CLH 205/SPH 244  4 units
- Biostatistics for Biomedical Science SPH 245  4 units
- Biostatistics for Clinical Research  SPH 246  4 units
  OR
- Statistical Analysis for Laboratory Data SPH 247  4 units
- Advanced Grant Writing  CLH 298  1 unit
- Team Science  CLH 298  1 unit
- Clinical Controversies CLH 290C  1 unit (required for 2 quarters)

**b) Elective Courses (6 units):** Elective requirements can be met with any combination of upper division or graduate courses in the biological or health sciences totaling 6 units. Elective units are chosen in consultation with the student Guidance Committee, and with approval of the CRGG Graduate Advisor.

**c) Summary:** A summary of the course requirements is outlined below, and is designed such that students can satisfy up to 10 course units in a Summer Session, held from July through August. The first core course (Clinical Epidemiology and Study Design) is held as a 1-week, 40-hour course during the first week of the session. The remaining summer core courses are taught over the next 6 weeks, with students meeting on Tuesdays and Thursdays.

<table>
<thead>
<tr>
<th>Course Requirements</th>
<th>Quarter</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Courses - Intensive Summer Session</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>• Clinical Epidemiology and Study Design (CLH 202)</td>
<td>Summer</td>
<td>3</td>
</tr>
<tr>
<td>• Introduction to Clinical Research (CLH 200)</td>
<td>Summer</td>
<td>3</td>
</tr>
<tr>
<td>• Methods in Clinical Research (CLH 203)</td>
<td>Summer</td>
<td>4</td>
</tr>
<tr>
<td>Core Courses – Academic Year</td>
<td></td>
<td>21</td>
</tr>
<tr>
<td>• Strategies for Grant Writing (CLH 201)</td>
<td>Fall</td>
<td>2</td>
</tr>
<tr>
<td>• Introduction to Medical Statistics (CLH 205/SPH 244)</td>
<td>Fall</td>
<td>4</td>
</tr>
<tr>
<td>• Biostatistics for Biomedical Science (SPH 245)</td>
<td>Winter</td>
<td>4</td>
</tr>
<tr>
<td>• Biostatistics for Clinical Research (SPH 246) OR Statistical Analysis of Laboratory Data (SPH 247)</td>
<td>Alt. Sp²</td>
<td>4</td>
</tr>
<tr>
<td>• Advanced Grant Writing (CLH 298)²</td>
<td>Winter</td>
<td>1</td>
</tr>
<tr>
<td>• Team Science (CLH 298)²</td>
<td>Spring</td>
<td>1</td>
</tr>
<tr>
<td>• Clinical Controversies (CLH 290C)</td>
<td>W/Sp</td>
<td>2 - 1/qtr.</td>
</tr>
<tr>
<td>• Responsible Conduct of Research (CLH 204)</td>
<td>F/W/Sp</td>
<td>3 – 1/qtr.</td>
</tr>
</tbody>
</table>

**Other Courses**
- Elective Courses (2-3 courses totaling 6 units) F/W/Sp  6

**Total Unit Requirements**  40
1 Course is currently 5 units, but was recently reconfigured to be a 4 unit course beginning Summer 2011. Approval for change in course units to be submitted Summer 2011.
2 Recently developed course; to be submitted for approval Summer 2011.
3 These two courses offered alternating Spring quarters. Students are required to choose one of these courses.

4) **Special requirements:** N/A

5) **Committees**

   a) **Admissions Committee:** Once the completed application materials are submitted, the application will be forwarded to the Admissions Committee. The Admissions Committee consists of three CRGG faculty. Based on a review of the entire application, a recommendation is made to accept or decline an applicant’s request for admission. That recommendation is forwarded to the Dean of Graduate Studies for final approval of admission. Notification of admissions decisions will be sent by Graduate Studies. Applications are accepted through May 31 for the next Summer entering class.

   b) **Student Guidance Committee:** Each student will have a Guidance Committee comprised of faculty Research Mentor(s), and one CRGG Graduate Advisor who will guide the student as they progress through the program. A student will typically have more than one Research Mentor. The Research Mentors will supervise the student’s research project and guide the student in the development of the study plan. The student’s research study plan is submitted at the time of application to the CRGG Admissions Committee. The CRGG Graduate Advisor will monitor the student’s research and degree program progress, and serve as a resource for policies and procedures. The student’s Guidance Committee will also be responsible for selecting the appropriate product (grant proposal or manuscript) for the student’s fulfillment of the written component of the capstone requirement (see Section 8).

   c) **Educational Policy and Curriculum Development Committee:** The Chair of this committee will be appointed by the Chair of the CRGG in consultation with the CRGG Executive Committee. The Educational Policy and Curriculum Development Committee will consist of the Chair and three additional members. As a subcommittee of the CRGG, it is charged with making recommendations regarding the educational policy and curriculum development of the program. The Educational Policy and Curriculum Development Committee will also have the responsibility of evaluating the final written and oral components of the capstone requirement for each student. If one of the committee members is also a research mentor for the student being evaluated, he/she will be recused from decisions regarding the fulfillment of the student’s written and oral capstone requirements.

6) **Advising Structure and Mentoring:** The Research Mentor is the faculty member who supervises the student’s research project and guides the student in the development of the study plan. As noted above, a student will typically have more than one Research Mentor. A CRGG Graduate Advisor, (CRGG Graduate Advisors are appointed by the Office of Graduate Studies), and the Research Mentors comprise the student’s Guidance Committee (see section 5) which monitors the student’s research and program progress, and is a resource for policies and procedures. The Graduate Program Staff assists

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1 We are requesting permission to admit students in the Summer Quarter as that is when they begin taking courses.
students with CCRG requirements and general university policies. The Mentoring Guidelines can be found on the School of Medicine Faculty Development website at: http://www.ucdmc.ucdavis.edu/facultydev/mentoring.html

7) Advancement to Candidacy: Every student must file a Candidacy for the Master’s Degree form after completing 50% of their course requirements, and at least one quarter before completing all degree requirements; this is typically the Winter quarter of the second year of the program for working professional students, or the Winter quarter of the first year of the program for full-time students. The Candidacy for the Degree of Master form can be found online at: http://www.gradstudies.ucdavis.edu/forms/. A completed form includes a list of courses the student will take to complete degree requirements. If changes must be made to the student’s course plan after s/he has advanced to candidacy, the student’s CRGG Graduate Adviser must recommend these changes to Graduate Studies. Students must have their CRGG Graduate Adviser sign the candidacy form before it can be submitted to Graduate Studies. If the candidacy is approved, the Office of Graduate Studies will send a copy to the appropriate graduate staff person and the student. If the Office of Graduate Studies determines that a student is not eligible for advancement, the department and the student will be told the reasons for the application’s deferral. Some reasons for deferring an application include: grade point average below 3.0, outstanding “I” grades in required courses, or insufficient units.

8) Capstone Requirement:

Completion of the oral and written capstone presentations is the last requirement of the M.A.S. Plan II. A student may complete the requirements once s/he has advanced to candidacy. However, it is important that the capstone requirement be completed at or near the end of the coursework for the Master’s degree; this is typically the Winter or Spring Quarter of the second year of the program for part-time working professional students, or the Winter or Spring Quarter of the first year of the program for full-time students.

The final capstone requirement will consist of both a written and oral presentation of the student’s mentored research project.

a) Written Component:

One of two types of written documents will be accepted to fulfill the capstone requirement. The choice of document will be that of the student’s Guidance Committee, and will be based on the career stage and level of research progress achieved by the student. The student is expected to work with his/her Research Mentor(s) to review and revise the written component before submission to the Education Policy and Curriculum Development Committee (see section c). The written component can be satisfied by one of the following, at the discretion of the Guidance Committee:

1. Independent research grant proposal to a federal agency (e.g. National Institutes of Health (NIH), CDC, DOE, etc.) or equivalent private foundation (e.g. American Cancer Society, Doris Duke Charitable Foundation, etc.). The format of the proposal must follow that of the federal PHS 398 form (Specific Aims and Research Strategy sections only) or National Research Service Award (NRSA) application, or an equivalent format for a private foundation grant application. The grant must represent the work of the student’s independent research, and not that of the Research Mentor(s).
2. First author manuscript (research, or review article in student’s area of research) formatted for a peer-reviewed journal. The manuscript must represent the student’s independent work, and be deemed suitable for publication by the student’s Guidance Committee and the Education Policy and Curriculum Development Committee.

b) Oral Component:

The oral component of the capstone requirement will take the form of a presentation before the Educational Policy and Curriculum Development Committee of the CRGG during the annual program retreat, which is also attended by other CRGG students, research trainees, and faculty mentors (approximately 50-75 total attendees). The presentation should be 15-20 minutes, and include the following components: 1) significance of the research, 2) specific aims, 3) methods, 4) results-to-date, 5) conclusions, and 6) future directions. There will be a question and comment period, following the presentation.

c) Evaluation of the Capstone Requirements:

The Educational Policy and Curriculum Development Committee will evaluate the final written and oral capstone products, and make recommendations to the CRGG Executive Committee. The committee’s unanimous vote is required to certify completion of the capstone requirement. Once the capstone requirement has been fulfilled, the Master’s Report Form will be signed by the Program Graduate Adviser and then forwarded to the Office of Graduate Studies. The deadlines for completing this requirement are listed each quarter in the campus General Catalog (available online at the website of the Office of the Registrar or from the Bookstore). A candidate must be a registered student or in Filing Fee status at the time the program submits the form, with the exception of the summer period between the end of the Spring Quarter and the beginning of Fall Quarter. The program must file the report with Graduate Studies within one week of the end of the quarter in which the student’s degree will be conferred.

9) Normative Time to Degree: The normative time from matriculation to degree is typically two years for working academic professionals, who are pursuing the degree part-time while performing clinical, teaching, and other work responsibilities. Students pursuing the M.A.S. degree full-time, who have no concurrent career or educational responsibilities, can meet requirements in one year (see example 1 and 2 year study plans in section 10). The one-year option requires full-time students to take 6 more units of coursework in one year than the part-time students, who have two years to complete the curricular requirements. The one-year option also requires a greater time commitment to research during the program year than that required of part-time professional students who are simultaneously balancing career responsibilities with graduate degree requirements. The viability of the one-year option is further facilitated by the requirement that mentor selections and research study plans are completed prior to application to the graduate group, allowing students to begin making research progress immediately upon entry into the program.
10) Typical Time Line and Sequence of Events:

Typical Two Year Plan for Part-Time Working Professionals

<table>
<thead>
<tr>
<th>Year One</th>
<th>Summer (10 units)</th>
<th>Fall (8 units)</th>
<th>Winter (8 units)</th>
<th>Spring (8 units)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Clinical Epidemiology and Study Design (CLH 202)</td>
<td>Biostatistics for Biomedical Science (SPH 245)</td>
<td>Biostatistics for Clinical Research (SPH 246)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Introduction to Clinical Research (CLH 200)</td>
<td>Responsible Conduct of Research (CLH 204)</td>
<td>OR Statistical Analysis of Laboratory Data (SPH 247)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Methods in Clinical Research (CLH 203)</td>
<td>Responsible Conduct of Research (CLH 204)</td>
<td>Responsible Conduct of Research (CLH 204)</td>
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<td></td>
<td></td>
<td>Clinical Controversies (CLH 290C)</td>
<td>Advanced Grant Writing (CLH 298)</td>
<td>Team Science (CLH 298)</td>
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<td></td>
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<td>Statistical Analysis</td>
<td>Capstone Oral and Written</td>
<td>Capstone Oral and Written</td>
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<tr>
<td></td>
<td></td>
<td>of Laboratory Data (SPH 247)</td>
<td>Requirements</td>
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<table>
<thead>
<tr>
<th>Year Two</th>
<th>Summer (0 units)</th>
<th>Fall (4 units)</th>
<th>Winter (4 units)</th>
<th>Spring (1 units)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Elective Course</td>
<td>Elective Course</td>
<td>Mentored Research (CLH299)</td>
<td>Mentored Research (CLH299)</td>
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<tr>
<td></td>
<td>Mentored Research (CLH299)</td>
<td>Mentored Research (CLH299)</td>
<td>Advancement to Candidacy</td>
<td>Capstone Oral and Written Requirements</td>
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<td></td>
<td></td>
<td></td>
<td>Capstone Oral and/or Written Presentation</td>
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</tr>
</tbody>
</table>
Typical One Year Plan for Full Time Students

<table>
<thead>
<tr>
<th>Year One</th>
<th>Summer (10 units)</th>
<th>Fall (11 units)</th>
<th>Winter (11 units)</th>
<th>Spring (8 units)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Elective Course</td>
<td>Elective Course</td>
<td>Biostatistics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Responsible Conduct of Research (CLH 204)</td>
<td>Responsible Conduct of Research (CLH 204)</td>
<td>for Clinical Research (SPH 246)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Strategies for Grant Writing (CLH 201)</td>
<td>Advanced Grant Writing (CLH 298)</td>
<td>OR Statistical Analysis of Laboratory Data (SPH 247)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Introduction to Medical Statistics (CLH 205/SPH 244)</td>
<td>Clinical Controversies (CLH 290C)</td>
<td>Responsible Conduct of Research (CLH 204)</td>
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<td></td>
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<td>Mentored Research (CLH 299)</td>
<td>Mentored Research (CLH299)</td>
<td>Team Science (CLH 298)</td>
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<td>Clinical Controversies (CLH 290C)</td>
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<td>Mentored Research (CLH299)</td>
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<td></td>
<td>Capstone Oral and Written Requirements</td>
</tr>
</tbody>
</table>

11) **Sources of Funding:** Most of our students are supported by their clinical home departments through release time, training grants and other internal and/or extramural training support.

12) **PELP, In Absentia and Filing Fee status:** Information about PELP (Planned Educational Leave), In Absentia (reduced fees when researching out of state), and Filing Fee status can be found in the Graduate Student Guide: [http://www.gradstudies.ucdavis.edu/publications/](http://www.gradstudies.ucdavis.edu/publications/)
Biostatistics Curriculum for the Masters Degree in Clinical Research

David Rocke, Laurel Beckett, Kyoungmi Kim, and Lihong Qi
Division of Biostatistics
Department of Public Health Sciences
School of Medicine

The biostatistics courses and requirements for the MAS in Clinical Research have been revised in response to the concerns of Graduate Council. There are four relevant courses for this degree program listed below, with the intended schedule of offerings:

SPH 244: Introduction to Medical Statistics (Fall)
SPH 245: Biostatistics for Biomedical Science (Winter)
SPH 246: Biostatistics for Clinical Research (Spring, Alternate Years)
SPH 247: Statistical Analysis for Laboratory Data (Spring, Alternate Years)

The suggested requirements are that all students take SPH 244 and SPH 245 or their equivalents, and one of SPH 246 and SPH 247 at their choice. The rationale for this is that all students engaged in clinical/translational research should understand basic to intermediate statistical methods, and that depending on the type of research that the student intends to pursue, further study in statistical methods for either clinical or laboratory studies is appropriate.

These courses currently are on the books in one form or another; the course descriptions have been revised to ensure better integration between courses, and there has been one exchange of course numbers to keep the courses in sequence.
Motivation: The curriculum for students in the Clinical Research Graduate Group (CRGG) includes courses that rely on a strong foundation of research methods in medicine or other health-related areas. Therefore, it is necessary for students to master the basic statistical methods that are most commonly used in medical research. This course has been developed to provide all the important concepts of classic statistical methods and worked-out examples from real medical research problems to illustrate these concepts.

Course Goals: The course is primarily aimed at graduate students and professional fellows in the CRGG who have already taken basic statistics (SPH 244: Introduction to Medical Statistics or the equivalent) and seek advanced knowledge of experimental design and statistical analysis – how to design a study to achieve research objectives and how to conduct an appropriate statistical analysis to extract the maximum amount of biological information from the data and thus obtain meaningful results. The course will focus on design and analysis techniques for biomedical studies. Concepts will be introduced and examples and exercises from the medical literature or actual medical research problems will be provided to illustrate these concepts. The main goal of the course is to familiarize the students with the statistical concepts most frequently used in the medical research, so that they master the statistical foundations of the analytic techniques they will be using for real medical research problems.

Specifically, this course is designed to help students understand Analysis of Variance (ANOVA) methods and regression methods for laboratory or clinical data. The major topics include experimental design, ANOVA, linear regression methods, logistic regression, and survival analysis for cohort data. Upon completing the course, students are expected to be able to:

- Understand how/when to appropriately use one-way ANOVA and two-way factorial design ANOVA in order to test equality of two or more means.
- Perform regression analysis procedures for assessing a predictor-outcome relationship, while controlling for multiple confounding variables, including
  - linear regression and multiple (multivariate) regression
  - logistic regression for a case-control study
  - survival analysis methods for cohort data (e.g., longitudinal or follow-up data)
- Apply these statistical techniques to real data.
- Interpret and critique the results of application of these statistical techniques as found in the medical literature.

Topical Outline:

<table>
<thead>
<tr>
<th>Lecture</th>
<th>Topic</th>
<th>Chapter (Rosner 2005)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Intro/Review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Types of experimental design</td>
<td></td>
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</tbody>
</table>

Type of Data, How to choose a proper statistical test (parametric vs.
Randomization for statistical inference & p-value

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>Regression and Correlation Methods</td>
<td>Ch 11</td>
</tr>
<tr>
<td>3</td>
<td>Multiple regression</td>
<td>Ch 11</td>
</tr>
<tr>
<td>4</td>
<td>2-sample t-test, regression, and ANOVA: Making connections</td>
<td>Ch 12</td>
</tr>
<tr>
<td>5</td>
<td>Design and Analysis of Factorial Experiments: 2-way ANOVA</td>
<td>Ch 12</td>
</tr>
<tr>
<td>6</td>
<td>Logistic regression for case-control data</td>
<td>Ch 13</td>
</tr>
<tr>
<td>7</td>
<td>Logistic regression</td>
<td>Ch 13</td>
</tr>
<tr>
<td>8</td>
<td>Logistic regression diagnostic performance (ROC curve)</td>
<td>Ref*</td>
</tr>
</tbody>
</table>
| 9 | Survival analysis:  
Censoring, survival, and hazard  
Nonparametric survival estimation: Kaplan-Meier | Ch 14 |
| 10 | Comparing survival curves: Log-rank test, | Ch 14 |
| 11-12 | Proportional hazards (Cox) model | Ch 14 |

**Prerequisites:** SPH 244 or the equivalent or consent of the instructor

**Grading and Course Requirements:** Grading is based on homework assignments (90%) and class attendance and participation in class (10%). Students receive a letter grade.

**References:** Examples for the class are extracted from medical and epidemiological journals including the *New England Journal of Medicine*, *Journal of the American Medical Association*, and the *American Journal of Epidemiology*. Textbook for the class includes:

- Survival Analysis (2nd ed.), Kleinbaum & Klein, Springer, 2005 (reference)

**Discussion/Lab:** Because it is desired that the statistical techniques become familiar enough that they are “routine” analyses, it is necessary that the students see and do many problems related to each topic. Homework and lecture are two opportunities for the students to work on problems, but the one hour of discussion per week is designed to provide even more time to work through problems related to the material presented that week. Students will be given a series of problems at the beginning of the discussion. They may work alone or in groups and the instructor will guide through problem-solving process. Towards the end of the discussion, students will present the solutions to the problems.
Motivation: Students in the Clinical Research Graduate Group (CRGG) will conduct clinical studies especially clinical trials in their research. It is critical for them to understand the fundamental principals of designs and statistical issues involved in clinical research so that they will be able to carry out well-designed studies. This course has been developed to walk the students through all important steps in conducting a clinical study with an emphasis on randomized clinical trials, from formulating the problem and designing the study to final statistical data analysis and reporting results.

Course Goals: The course is primarily designed for graduate students and professional fellows in the CRGG who have already learned basic statistical concepts and various analysis methods (SPH 244: Introduction to Medical Statistics or the equivalent and SPH 245: Biostatistics for Biomedical Science). The course aims at helping students to develop understanding for various aspects of designing and conducting clinical studies with an emphasis on randomized clinical trials and statistical issues involved at each study stage. The main purpose of the course is not to introduce new statistical methods but to prepare the students to be able to conduct well-designed clinical studies, and to work with biostatisticians in their research more effectively.

Upon successful completion of the course, the students will become familiar with fundamental principals of both the design and the analysis of a clinical study, and be able to handle simple statistical issues involved at different stages of randomized clinical trials including study design, monitoring, interim and final data analysis. Specifically, the students are expected to be able to:

- Familiar with steps in conducting a clinical trial
- Understand various type of clinical trials, the advantage of randomized clinical trials, and common used randomization approaches
- Formulate the study problem, including
  - developing specific hypotheses
  - identifying proper study population and endpoints (primary, secondary, etc)
  - calculating sample size and power for various types of endpoints
- Know how to develop a study protocol and monitor trial process
- Distinguish different types of data and different parametric and nonparametric statistical tests, choose proper analysis methods based on the data type and carry out simple exploratory and definite statistical analyses
- Understand issues in recruitment, retention and protocol adherence and reporting results
- Apply the course materials to their own medical research

Topical Outline:

<table>
<thead>
<tr>
<th>Lecture</th>
<th>Topic</th>
</tr>
</thead>
</table>
| 1       | Course Introduction  
definition and phases of clinical trials  
steps of conducting an experimentation |
| 2       | Types of clinical trials  
Formulating the problem 1: the question, the intervention,  
the response variables, the population and the design |
Formulating the problem 2: sample size calculation for continuous outcomes

Formulating the problem 3: sample size calculation for binary outcomes

Formulating the problem 4: sample size calculation for survival outcomes

Developing a written study protocol and randomization

Forms and data management
Monitoring of trial process
Interim analysis and sequential design

Data analysis 1: first look at your data
Methods for continuous and categorical response

Data analysis 2: other methods including ROC and Cox model for survival data

Issues in data analysis
Close out
Reporting and interpreting results
Review of the course

Prerequisites: SPH 244 and SPH 245 or the equivalent or consent of the instructor

Grading and Course Requirements: Grading is based on homework assignments (70%), class attendance and participation in class (20%) and a final report (10%). Students receive a letter grade.

References: Materials and examples for the class are extracted from medical and epidemiological journals and online resources. Textbooks include:

Other reference:
- Chow, Shao and Wang “Sample size calculations in clinical research”, 2003, Taylor & Francis

Discussion/Lab: The course is designed to be very interactive between students and instructors with a lot of hands-on opportunities for the students. During discussion/lab time, students will be given computing examples and exercises to practice what they have learned in lectures. They may work alone or in groups and the instructor will guide through problem-solving process. Towards the end of the discussion, students will present the solutions to the problems.
**SPH 247**  
*Statistical Analysis for Laboratory Data*  
4 units (3 hours of lecture, 1 hour of discussion)

**Motivation:** The curriculum for students in the Clinical Research Graduate Group (CRGG) includes required courses that rely on a strong foundation of research methods in medicine or other health-related areas. In addition, there are two elective courses that cover material specific to the research agenda of the student. This course has been developed to provide the important concepts involved in the statistical analysis of laboratory data, including results from PCR, immunoassay, mass spectrometry, gene expression arrays, and other methods.

**Course Goals:** The course is primarily aimed at graduate students and professional fellows in the CRGG who have already taken the two fundamental statistics classes (SPH 244: Introduction to Medical Statistics or the equivalent and SPH 245 Biostatistics for Biomedical Science) and seek advanced knowledge of statistical methods for analysis of laboratory data.

Specifically, this course is designed to help students understand Analysis of Variance (ANOVA) methods and regression methods for laboratory or clinical data. The major topics include experimental design, ANOVA, linear regression methods, logistic regression, and survival analysis for cohort data. Upon completing the course, students are expected to be able to:

- Understand how/when to appropriately use one-way ANOVA and two-way factorial design ANOVA in order to test equality of two or more means.
- Perform regression analysis procedures for assessing a predictor-outcome relationship, while controlling for multiple confounding variables, including
  - linear regression and multiple (multivariate) regression
  - logistic regression for a case-control study
  - survival analysis methods for cohort data (e.g., longitudinal or follow-up data)
- Apply these statistical techniques to real data.
- Interpret and critique the results of application of these statistical techniques as found in the medical literature.

**Topical Outline:**

- Experimental design for laboratory studies, including multifactorial designs, randomization, blocking, analysis of inter-and intra-laboratory sources of variation.
- Introduction to assays, calibration curves (linear, log-logistic and others).
- Application of regression, logistic regression, and ANOVA to laboratory data.
- Western blots, PCR, and other single compound assays.
- Multivariate analysis of laboratory data, including PCA, clustering, and discriminant analysis.
• Gene expression arrays and the analysis of data from them, including specifics of the Affymetrix and Illumina platforms, normalization, data transformation, identification of differentially expressed genes, correction for multiple testing.

• Gene and protein annotation, including use of GO, KEGG, EntrezGene, DAVID, and other tools.

• Classification using biological samples, including variable (feature) selection, prediction using logistic regression, discriminant analysis, SVMs and other methods, cross validation, ROC curves.

**Prerequisites:** SPH 245 or the equivalent or consent of the instructor

**Grading and Course Requirements:** Grading is based on homework assignments (90%) and class attendance and participation in class (10%). Students receive a letter grade.