Regulatory Issues in Drug Research  
ECP 5220 (2 credit)  
Fall 2016  
SYLLABUS

Course Director:  
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Preferred method of contact: email

Office Hours: By appointment

Course Times: 8:00-9:55

Location: 7-103 WDH

Course Overview: This course is meant to expose the student to regulatory issues encountered in conducting drug research trials. At the end of this course students will have the minimal training required by the University of Minnesota in order to perform different aspects of clinical trials. Materials will be presented through lectures, readings, small group discussions, and homework assignments.

Course Objectives:

1) Present aspects of training needed in order to participate in various areas of clinical trial research

2) Complete all the necessary training required to begin developing and working on experimental and clinical research projects at the University of Minnesota.

3) Recognize and identify the regulatory steps needed at the University and federal level in order to conduct clinical research.

4) Identify regulatory needs and issues from the perspective of the subject, institution, sponsor, and investigator.

5) Determine how to create a viable research design in regards to regulatory issues including study sample, population, and budgetary domains.

6) Understand the composition and review process of an Institutional Review Board Human Subjects Committee.

Use of Technology
Students are expected to use Moodle to access course information and grade information. E-mail via university email accounts will be used to communicate with students. Students are expected to check their e-mail on a daily basis for class announcements.
Grading
Grades will be determined on a point system where each in-class and homework assignment is allocated a number of points. There will be a number of reading and writing assignments. A final exam consisting of multiple choice and essays questions will be given. Exam(s) will make up 25%, class participation 15%, training assignments 30%, and homework assignments 30% of the grade.

Grades will be based on the following scheme:

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<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A</td>
<td>&gt; 93%</td>
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<tr>
<td>A-</td>
<td>90-92</td>
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<tr>
<td>B+</td>
<td>87-89</td>
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<tr>
<td>B</td>
<td>83-86</td>
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<tr>
<td>B-</td>
<td>80-82</td>
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<tr>
<td>C+</td>
<td>77-79</td>
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<td>C</td>
<td>73-76</td>
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<td>C-</td>
<td>70-72</td>
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<td>D</td>
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<td>F</td>
<td>&lt; 60</td>
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Late assignment Policy: Assigned readings are expected to be read before in-class time so that students can fully participate in classroom discussions. Assignments handed in late will have 10% of the total assignment points deducted for each day late after the day the assignment is due (5 pm deadline).

Confidentiality: During this course, protocols, manuscripts, cases, and budgets from various investigators may be shared with the class. Frequently, the investigators sign confidentiality statements when participating in these studies. As a student in this class, you will be expected to keep confidential any unpublished protocol designs or manuscripts and all budgets shared with you.

Course and Make-up Policies:
Make-up assignments and project presentations will only be re-scheduled for the following reasons: illness (verified by note from a physician); a family emergency (verified by note from a professional in attendance); a University-sponsored event (verified by a University official or a note from the leader of the sponsoring organization); military duties (verified by a note from a commander). All excused absences must be arranged with the Course Director(s) in advance of the regularly scheduled class. If you become sick or a family member becomes sick, or if there is a serious family emergency, please contact the course director as soon as possible.

Disability Accommodation:
The University of Minnesota is committed to providing all students equal access to learning opportunities. Disability Services is the campus office that works with students who have disabilities to provide and/or arrange reasonable accommodations. Students registered with Disability Services, who have a letter requesting accommodations, are encouraged to contact the instructor early in the semester. Students who have, or think they may have, a disability (e.g. psychiatric, attentional, learning, vision, hearing, physical, or systemic), are invited to contact Disability Services for a confidential discussion at 612-626-1333 (V/TTY) or at ds@umn.edu. Additional information is available at the DS website http://ds.umn.edu.