Design and Management of Field Studies in Epidemiology
Course No. 26-BE-9075
3 Graduate Credits
“Foster a healthy disregard for the impossible”

Professors: Erin Haynes, DrPH, MS (558-5427), Room G32, Kettering
           erin.haynes@uc.edu
           Patrick Ryan, PhD (803-4704), CCHMC S10.413
           patrick.ryan@cchmc.org
           If in need of urgent response please call one of us.

Class:       Tuesdays: 12:20-3:00 PM, Room G17 Kettering Lab

Office Hours: Tuesdays: 3:00-4:00 PM, Peer group conferences.

             Lippincott Williams & Wilkins. Older additions are similar
             Strunk, W. and White, E.B. The Elements of Style. 4th Ed. 2000. (~$12.00) You are also
             evaluated on written style including paragraph and sentence structure.
             Cheaper texts available at amazon.com

Course pack. All supplemental reading and handouts have been combined. See Megan Parin, Room G36C Kettering
             Personal check or cash only (~$10.00)

Course Objectives:
The course objectives include the following:
• acquire knowledge and skills in formulating a research question,
• learn to critique and interpret scientific literature
• develop the hypothesis and specific aims
• create an appropriate plan of investigation
• write a mini research proposal
• learn the NIH methods for evaluating research.

Class sessions will address core issues relevant to each step in the research process. You should learn to
write in a crisp, clear and succinct manner. Attention should be given to the following:
• a thorough review of the literature
• using the optimum study design
• understanding the assumptions made when calculating sample size
• utilizing sampling methodologies
• characterizing independent and dependent variables
• measuring reliability and validity
• understanding the NIH process for critiquing research.

Research is a creative process, both an art and a science. Enjoy!
**Course Requirements:**

1. Weekly reading assignments, class attendance, and class participation. Much of the subtle finer points of research proposal development will come from the oral exchange in class. Your learning will be proportional to your participation. If you are on call please put phone/pagers on vibrate.
2. Submission of homework assignments. Homework is designed to provide you with ongoing feedback.
3. Evaluation of a classmate’s research proposal using the NIH peer review method.

NIH R21-like Proposal
Details provided on following pages.

NIH Peer Review Critique
On the last day of class everyone will turn in their final proposal. Each student will be randomly assigned someone else’s research proposal just as if you are a member of a study section. Your score will be based on the critique of your fellow student’s proposal.

The review and score given by you, the reviewer, will only be used to evaluate your knowledge and skill for evaluating another’s research and writing skills. **It is very important that you arrive to class on time during this in class review session.** We will be randomly assigning each proposal to another student, and the late arriver’s proposal will be given to someone who has already started the review process of another proposal – making them an unhappy review, right off the bat! **If you are unable to be at class on this date or due to other demands cannot complete your proposal on time then it is suggested that you drop this class for now.**

**Presentation**
Students will prepare a 10 minute presentation of their research proposal and present it during class as if they were presenting at a national/international conference. The presentation should include the following elements: background, significance, hypothesis, specific aims, and methods. Presentations will be videotaped and students will be provided a link to their presentation for reflection.

**Course Grade:**

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<th>Component</th>
<th>Percentage</th>
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<tr>
<td>Homework</td>
<td>10%</td>
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<tr>
<td>Presentation</td>
<td>10%</td>
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<tr>
<td>NIH Peer Review Critique</td>
<td>20%</td>
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<tr>
<td>NIH R21 Proposal</td>
<td>60%</td>
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**Academic Ethics:** The faculty of the Department of Environmental Health believe that the conduct of a student taking a course in the Department should be consistent with that of a professional individual. All students in this course will be expected to conduct themselves with complete integrity. All work by the student will be the work of that student, unless otherwise referenced. All work presented and shared by students will be considered their work and not used by another student unless a collaboration is determined.

**Snow/Emergency Day Policy:** UC may close one or more campuses as needed due to severe winter weather. A closure may affect one or more of our campuses, and may be for an entire day, or part of a day. University closings are announced to all students and employees through multiple methods:
* emergency email
* via web at [www.uc.edu](http://www.uc.edu)
* text message to everyone who has signed up to receive emergency messages
* recording on the campus status line at (513) 556-3333
* recording at the main campus number at (513) 556-6000
* via most Cincinnati broadcast news media

**IF there is a closure during our regular class meeting time, we will NOT meet for class that day.**
Proposal Submission Outline

Use this as a guide to submit your final proposal. It is based on NIH guidelines, but revised for this course. **All bold, underlined terms are required, and will be used to determine your proposal grade.** Refer to your syllabus and class lectures, and adjust to suit your proposal. You will also be graded on writing style and organization. The proposal that you turn in will be based on the NIH R21 award guidelines with some exceptions noted below. The instructions below are what are required for this class - be sure to follow these guidelines carefully. Each numbered section below should start on a new page. **We will follow NIH requirements for margins and font (11 pt Arial font, single-spaced, ½” margins).**

1. NIH Face Page 1 **(title, your name and contact)**

2. **Project Summary (Abstract)** (31 lines)
   - Summarize your proposed research
   - Briefly provide background/rationale, outline the hypothesis and specific aims, and research design
   - Briefly provide information on significance and innovation

3. **Project Narrative**
   - 2-3 sentences to describe the relevance of the research to public health
   - Use easy to understand language appropriate for lay audience

4. NIH Biosketch

5. **Specific Aims Page (1 Page Limit)**
   - State concisely the goals of the proposed research and summarize the expected results, including the impact that the results of the proposed research will exert on the research field(s) involved.
   - List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
   - Use selective bolding, italics and/or underlining to emphasize the hypothesis and specific aims.

   The research strategy must include the following three sections (each separately labeled): A) Significance, B) Innovation, and C) Approach. The entire Research Strategy may not exceed 3 single spaced pages for this class (NIH guidelines allow for 6 or 12 pages for R21 and R01 applications, respectively)

**A. Significance**
- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved
- Incorporate your relevant literature review as background and supporting information in this section
- State clearly the public health significance of your proposal and once successful how your project will positively impact/improve public health.

**B. Innovation**
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions

**C. Approach**
• Preliminary studies/data. Provide a description of Preliminary Studies using data that YOU have gathered. Discuss the PD/PI’s preliminary studies, data, and or experience pertinent to this application.

• A clear description of the study design. Describe the overall strategy, methodology, and analyses to be used to accomplish the aims of your project.
  - A clear description of the study population including inclusion/exclusion criteria
  - A clear definition of outcome and predictive variables

• Descriptions of research tools and their reliability/validity, and methods to address quality control and quality assurance. Include information on how the data will be collected, analyzed, and interpreted. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Point out any procedures, situations, or materials, if any, that may be hazardous to personnel and precautions to be exercised.
  - Include statistical analysis, including sample size

• Include a limitations section: description of potential bias – stating potential confounders and how these will be handled. Discuss potential problems, alternative strategies, and benchmarks/timelines for tasks to be completed to achieve the aims.

7. Additional Requirement Material to Accompany your Grant Application (NOT part of page limitation): Tables/Figures and Timeline are incorporated within the 6 page Research Strategy of a NIH R21; however, for this class, we are NOT counting them towards your 3 page limit.

A. Figure/Tables

B. Timeline

C. Budget and Budget Justification

D. References

E. Literature review table
<table>
<thead>
<tr>
<th>DATE</th>
<th>TOPIC</th>
<th>SPEAKER</th>
<th>IN-CLASS EXERCISE</th>
<th>READINGS/ HOMEWORK (READINGS DUE FOR THE NEXT CLASS &amp; ASSIGNMENTS TO BE SUBMITTED VIA BLACKBOARD DROPBOX UNLESS OTHERWISE SPECIFIED)</th>
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| 1/13/15  | -Class expectations                                                  | Haynes                   | Example of ‘Research Postcard’                                                    | 1. Readings for 1/20/15  
- Chapters 1 and 2  
- Hamada and Sitter, 2004 (in course pack)  
- Inouye and Fiellin, 2005 (in course pack)  
- Banerjee et. al., 2009 (in course pack)  
2. Go to NIH RePORTER website. Find studies similar to yours, collect the abstract(s), and state how your project is unique and will expand the field.  
-Due 1/19/15, 11:59pm, Bb Dropbox  
3. Submit in pencil on a 4X6 index card A) research problem, B) research question, and C) research purpose. On the opposite side, create an artistic reflection of your research.  
-Due 1/20/15, in class |
|          | -Overview of NIH R21 grant                                           | Special guest: Jennifer Kaplan Kopras |                                                                                 |                                                                                                                            |
|          | -Research problem/question                                           |                          |                                                                                 |                                                                                                                            |
|          | -Which grants are right for you?                                     |                          |                                                                                 |                                                                                                                            |
| 1/20/15  | -The power of a team                                                | Haynes                   | Identify your independent and dependent variables  
Hypothesis writing & group peer review | 1. Write your hypothesis  
-Due 1/26/15, 11:59pm, Bb Dropbox |
|          | -Independent (predictor) & dependent (outcome) variables             | Special guest: Nicole Sheannon Ryan |                                                                                 |                                                                                                                            |
|          | -Writing a hypothesis                                               |                          |                                                                                 |                                                                                                                            |
|          | -Literature Review                                                   |                          |                                                                                 |                                                                                                                            |
|          | -References                                                          |                          |                                                                                 |                                                                                                                            |
| 1/27/15  | -Writing strong specific aims                                       | Ryan                     | Review hypothesis  
Writing specific aims & group peer review | 1. Readings for 2/3/15  
- Chapters 4, 16, & 17  
2. Reliability homework (in course pack)  
-Due 2/2/15, 11:59pm, Bb Dropbox |
<p>|          | -Significance                                                        | Haynes                   |                                                                                 |                                                                                                                            |
|          | -Innovation                                                          |                          |                                                                                 |                                                                                                                            |
|          | -Writing specific aims page                                         | Ryan                     |                                                                                 |                                                                                                                            |</p>
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<th>Reading Source</th>
<th>Additional Information</th>
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| 2/3/15    | Assessing & improving reliability & validity                         | LeMasters                       | 1. Readings for 2/10/15  
- Chapters 7-12 & 18 and Table  
2. Complete your specific aims page  
-Due 2/9/15, 11:59pm, Bb Dropbox  
3. Complete CITI Training; Become a CCTST member:  
-http://cctst.uc.edu/  
-Turn in completion report  
-Due 2/9/15, 11:59pm, Bb Dropbox |
| 2/10/15   | Approach  
- Preliminary studies  
- Study design and statistical methods  
- Study design figure                  | Haynes                          | 1. Readings for 2/17/15  
- Chapter 3  
2. Study design figure  
-Due 3/2/15, 11:59pm, Bb Dropbox |
| 2/17/15   | Sampling strategies & participant recruitment                        | Ryan                            | 1. Readings for 2/24/15  
- Chapters 5 & 6  
- Whitley and Ball, 2002 (in course pack)  
2. Sample size worksheet (in course pack):  
- Select and calculate the formula you think is correct  
- Write out your current hypothesis statement on the worksheet  
- Bring your calculator to class next week  
-Due 2/24/15, in class  
3. Significance & innovation sections  
-Due 2/23/15, 11:59pm, Bb Dropbox  
4. Complete the statistical approach worksheet (found on Bb)  
-Due 3/3/15, in class |

Special guest: Justin Benoit  
Ryan  
Ambroggio
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<th>Date</th>
<th>Topic</th>
<th>Resource</th>
<th>Due Date</th>
<th>Notes</th>
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<td></td>
<td>-Statistical analysis</td>
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<td>-Harris et. al., 2009</td>
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<td></td>
<td>-Avoiding loss to follow-up</td>
<td>Hilbert</td>
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<td>-Due 3/2/15, 11:59pm, Bb Dropbox</td>
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<td>-Data management/REDCap</td>
<td>REDCap administrator</td>
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<td>-QA/QC methods</td>
<td>Haynes/Ryan</td>
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<td>-Strengths and limitations</td>
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<td>-Writing a strong title</td>
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<td>-Project narrative</td>
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<td>-Abstract</td>
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<td>-Timeline</td>
<td>Ryan</td>
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<td>-How to be a Member of an R01 NIH Study Section (in course pack)</td>
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<td>-Budget:</td>
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<td>-Mock grant proposal (distributed in class)</td>
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<td>-NIH</td>
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<td>-What we expect for this class</td>
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<td>-Ethics</td>
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<td>3/17/15</td>
<td>SPRING BREAK – No Class</td>
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<td>3/24/15</td>
<td>NIH grant peer review</td>
<td>Dietrich</td>
<td>3/31/15</td>
<td>1. Readings for 3/31/15</td>
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<td>-Scientific review:</td>
<td>Haynes</td>
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<td>-Burroughs Welcome Fund, Communicating Science: Giving Talks</td>
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<td>-What we expect for this class</td>
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<td>2. NIH review of mock grant proposal</td>
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<td>3. Organize your full proposal for an in-class review</td>
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<td>-Due 3/31/15, in class</td>
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| 3/31/15 | - Communicating your research                                             | I Yancey Mock grant review  
|         | - Effective presentations                                                | Review of proposal  
|         | - Review of proposal                                                     | 1. Finalize your presentation  
|         |                                                                          | - Due either 4/6/15 or 4/13/15, 11:59pm, Bb Dropbox & save a copy on your flashdrive & bring to class on 4/7/15 & 4/14/15 |
| 4/7/15  | Student presentations                                                    | Prepare feedback for each presentation  
| 4/14/15 | Student presentations                                                    | Prepare feedback for each presentation  
|         |                                                                          | 1. Prepare for the final “exam”  
|         |                                                                          | - Prepare your final proposal following the guidelines outlined in the course pack  
|         |                                                                          | - Due 4/21/15, 11:59 am, Bb Dropbox & bring a hard copy to the final “exam” peer review  
|         |                                                                          | - Be prepared to review a peer’s proposal using the NIH review scoring criteria provided in the course pack  
|         |                                                                          | - Bring several #2 pencils and an eraser to class next week  
| 4/21/15 | Final “exam” peer review/study section                                   | Peer review of the full grant proposal  
| 4/28/15 | No class - Relax and have a great summer!                                |                                                                     |