Design & 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), Rm. G32, Kettering  
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Patrick Ryan, PhD (803-4704), CCHMC, S10.413  
patrick.ryan@cchmc.org

If in need of an urgent response, please call one of us.

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

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


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 www.amazon.com

Course pack. All supplemental reading and handouts have been combined. See Emma Jones, Kettering, Rm. G32  
Cash preferred (~$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 to discussion board. Homework is designed to provide you with ongoing feedback. To submit to discussion board, click on the forum name, then click “create thread”.
3. Peer review of classmate’s homework assignments in blackboard located on discussion board.
4. Evaluation of a classmate’s research proposal using the NIH peer review method.
5. Submission of NIH R21-like formatted proposal (details attached).

**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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<tr>
<th>Component</th>
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<tr>
<td>Homework/Discussion Board Peer Review</td>
<td>20%</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>
</tr>
<tr>
<td>NIH R21 Proposal</td>
<td>50%</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.

6. Research Strategy (3 Page Limit, Single Spaced)
   The research strategy must include the following three sections (each separately labeled):
   A) Significance
   B) Innovation
   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>
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<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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</table>
| 1/10/17 | ▪ Class expectations                                                | Haynes      | Example of ‘Research Postcard’                                                    | 1. Readings for next class:  
▪ Chapters 1 & 2  
▪ Hamada and Sitter, 2004 (in course pack)  
▪ Inouye and Fiellin, 2005 (in course pack)  
▪ Banerjee et. al., 2009 (in course pack)  
▪ Baker, 2015 (in course pack)  
2. Go to NIH RePORTER website. Find 2-3 studies that are similar to yours; collect the abstracts, provide which NIH Institute and program officer. State how your project is unique and will expand the field.  
▪ Due day before next class, 11:59pm, Bb Dropbox  
3. Submit in pencil on a 4X6 index card: A) research problem, B) research question, & C) research purpose. On the opposite side, create an artistic reflection of your research.  
▪ Due at beginning of next class, hardcopy |
|         | ▪ Overview of NIH R21 grant                                            |             |                                                                                 |                                                                                                                                  |
|         | ▪ Research problem/question                                           |             |                                                                                 |                                                                                                                                  |
|         | ▪ The power of a team                                                | Ryan        |                                                                                 |                                                                                                                                  |
|         | ▪ Literature Review                                                  |             |                                                                                 |                                                                                                                                  |
|         | ▪ References                                                         |             |                                                                                 |                                                                                                                                  |
| 1/17/17 | ▪ Independent (predictor) & dependent (outcome) variables             | Haynes/Veevers | Identify your independent & dependent variables Peer review of note cards      | 1. Write and post your hypothesis and specific aims  
▪ Due day before next class, 11:59pm, Bb Discussion Board  
2. Write and post your significance & innovation sections  
▪ Due day before next class, 11:59pm, Bb Discussion Board  
3. Peer Review: Comment on 3 hypotheses and 3 specific aims posts on discussion board. Provide thoughtful, constructive criticism.  
▪ Due day before next class, 11:59pm, Bb Discussion Board  
4. Reliability homework (in course pack)  
▪ Due next class, hardcopy |
|         | ▪ Writing a hypothesis and strong specific aims                      |             |                                                                                 |                                                                                                                                  |
|         | ▪ Writing specific aims page                                         | Ryan        |                                                                                 |                                                                                                                                  |
| 1/24/17 | ▪ Significance                                                        | Ryan        | Hypothesis peer review Specific aims peer review                               | 1. Readings for next class:  
▪ Chapters 4, 16, & 17  
2. Write and post your significance & innovation sections  
▪ Due day before next class, 11:59pm, Bb Discussion Board  
3. Peer Review: Comment on 3 hypotheses and 3 specific aims posts on discussion board. Provide thoughtful, constructive criticism.  
▪ Due day before next class, 11:59pm, Bb Discussion Board  
4. Reliability homework (in course pack)  
▪ Due next class, hardcopy |
<p>|         | ▪ Innovation                                                          | Haynes/Veevers |                                                                                 |                                                                                                                                  |
|         |                                                                      |             |                                                                                 |                                                                                                                                  |</p>
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| 1/31/17   | ▪ Assessing & improving reliability & validity  
▪ Laboratory QA/QC | Brunst           | Significance & innovation peer review  
Reliability and validity exercise, (have your homework ready to review in class) | 1. Readings for next class:  
▪ Chapters 7, 12 & 18  
2. Watch online module in Blackboard  
3. **Peer Review:** Comment on 3 significance and 3 innovation sections on discussion board. Provide thoughtful, constructive criticism.  
▪ **Due day before next class, 11:59pm, Bb Discussion Board**  
4. Complete CITI Training; Become a CCTST member  
▪ [http://cctst.uc.edu/](http://cctst.uc.edu/)  
▪ Turn in completion report  
▪ **Due day before next class, 11:59pm,** |
| 2/7/17    | ▪ Study design & statistical methods  
▪ Study design figure  
▪ Confounding & interaction  
▪ Causal inference | Ryan/Ambroggio   | Study design figure  
|          |                                          |                  | 1. Readings next class:  
▪ Chapters 5 & 6  
▪ Whitley and Ball, 2002 (in course pack)  
▪ Banerjee and Chaudhury, 2010 (in course pack)  
2. Create and post your Study Design Figure  
▪ **Due day before next class, 11:59pm,** Bb Discussion Board | |
| 2/14/17   | ▪ Approach  
▪ Timeline & Milestones  
▪ Limitations & Alternative Approaches  
▪ Recruitment  
▪ Preliminary Studies | Ryan           | Study design figure peer review  
Name & describe 3 sources of preliminary data for your study | 1. Readings for next class:  
▪ Chapter 3  
▪ Harris et. al., 2009 (in course pack)  
2. Write and post your approach section  
▪ **Due day before next class, 11:59pm,** Bb Discussion Board  
3. **Peer Review:** Comment on 3 study design figures on discussion board. Provide thoughtful, constructive criticism.  
▪ **Due day before next class, 11:59pm,** Bb Discussion Board |
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| 2/21/17  | ▪ Data management/REDCap  
▪ Writing a strong title  
▪ Project narrative  
▪ Abstract  
▪ Budget:  
  - NIH  
  - What we expect for this class | Haynes/Veevers | Approach section peer review  
Budget exercise – complete budget during class | 1. Watch online module in Blackboard  
2. Write and post your title and abstract  
  ▪ Due day before next class, 11:59pm, Bb Discussion Board  
3. **Peer Review:** Comment on 3 approach sections on discussion board. Provide thoughtful, constructive criticism. **Due day before next class, 11:59pm, Bb Discussion Board**  
4. Sample size worksheet (in course pack):  
  ▪ Watch online video prior to class  
  ▪ Select & calculate the formula you think is correct  
  ▪ Write out your current hypothesis statement on the worksheet  
  ▪ Bring the manuscript/data used to determine your effect size  
  ▪ Bring your calculator to class next week  
  ▪ **Due at beginning of next class, hardcopy** |
| 2/28/17  | ▪ Approaches to determine sample size power  
▪ Statistical analysis | Sucharew      | Sample size calculation  
Statistical approach mini consultation | 1. Readings for next class:  
  ▪ Chapters 14 & 19  
  ▪ Ferguson et. al., 2014 (in course pack)  
How to be a Member of an R01 NIH Study Section (in course pack) |
| 3/7/17   | ▪ NIH review for class  
▪ NIH grant peer review | Haynes  
Dietrich   | Peer review titles & abstracts | 1. **Peer Review:** Comment on 3 titles and 3 abstracts on discussion board. Provide thoughtful, constructive criticism.  
  ▪ **Due day before next class, 11:59pm, Bb Discussion Board**  
2. Write and post your literature review and timeline  
  ▪ **Due day before next class, 11:59pm, Bb Discussion Board** |
| 3/14/17  | **SPRING BREAK - NO CLASS**                                             |               |                                                            | Finalize your presentation – email Emma Jones, emma.jones@uc.edu, for uploading prior to class. |
## DESIGN & MANAGEMENT OF FIELD STUDIES IN EPIDEMIOLOGY CLASS SCHEDULE *(subject to change)*

<table>
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<tbody>
<tr>
<td>3/21/17</td>
<td>Student presentations</td>
<td></td>
<td>Prepare feedback for each presentation</td>
<td>1. <strong>Peer Review:</strong> Comment on 3 literature reviews and 3 timelines on discussion board. Provide thoughtful, constructive criticism.</td>
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<td>- Due day before next class, 11:59pm, Bb Discussion Board</td>
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<tr>
<td>3/28/17</td>
<td>Student presentations</td>
<td></td>
<td>Prepare feedback for each presentation</td>
<td>1. Mock grant proposals (distributed over email)</td>
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<td>- Due during next class, bring hardcopy</td>
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<tr>
<td>4/4/17</td>
<td>NIH Mock Study Section</td>
<td>Haynes</td>
<td>Mock grant review</td>
<td>1. Readings for next class:</td>
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<td>- Burroughs Welcome Fund, Communicating Science: Giving Talks</td>
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<tr>
<td>4/11/17</td>
<td>K Class</td>
<td>Tsevat/ Veevers</td>
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<td>1. Prepare for the final “exam”</td>
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<td>- Prepare your final proposal following the guidelines outlined in the course pack</td>
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<td>- <strong>Due in hard copy next class</strong></td>
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<td>- Be prepared to review a peer’s proposal using the NIH review scoring criteria provided in the course pack</td>
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<td>- Bring several #2 pencils &amp; an eraser to class next week</td>
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<tr>
<td>4/18/17</td>
<td>Final “exam” peer review</td>
<td></td>
<td>Peer review of the full grant proposal</td>
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<tr>
<td>4/25/17</td>
<td>No class!</td>
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<td></td>
<td>Relax &amp; have a great summer!</td>
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