Fall 8-1-2018

EPID 8230 – Observational Study Design and Analysis

Kelly L. Sullivan

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Georgia Southern University  
Jiann-Ping Hsu College of Public Health  
EPID 8230 – Observational Study Design and Analysis  
Fall 2018

| Instructor: | Kelly Sullivan, Ph.D. |
| Office:     | Hendricks Hall, Room 2040 |
| Phone:      | (912) 478-7902 (best to contact me by email) |
| E-Mail Address: | ksullivan@georgiasouthern.edu (to set up an appointment) |
| Office Hours: | Tuesday and Thursday 9am – 12pm and by appointment |

**Prerequisites:** N/A

**FOLIO address:** [http://my.georgiasouthern.edu](http://my.georgiasouthern.edu)

**Catalog Description**

This course will focus on the design and conduct of observational research designs including cohort, case-control and cross-sectional approaches. This course will provide instruction related to issues specific to observational research approaches. Students will develop and present detailed study plans for each research approach.

**Required Textbook:**

Critical appraisal of epidemiological studies and clinical trials, 4th Edition  
Elwood, M.  

Additional Required readings will come from journal articles.
DrPH Core Student Learning Outcomes

1. Demonstrate their readiness to work with communities to address public health problems.
2. Select and apply theoretically based interventions to address public health problems.
3. Apply appropriate research methods to address community health problems, particularly among rural and underserved populations.

DrPH Concentration Competencies

1. Construct a public health and epidemiological research question from ideas, conditions, and events that exist in a rural and urban community, region, state, and nation using critical thinking skills.
2. Demonstrate required skills for translating public health practice objectives to the appropriate epidemiological framework for analysis and interpretation of results.
3. Select appropriate statistical tools, methodological alternatives, and graphical descriptives to analyze and summarize public health and epidemiological data.
4. Formulate population-based hypotheses and develop appropriate research designs to test these hypotheses.
5. Communicate epidemiological principles and concepts to lay and professional audiences through both oral and written communication.

CEPH DrPH Competencies

Data & Analysis
1. Explain qualitative, quantitative, mixed methods and policy analysis research and evaluation methods to address health issues at multiple (individual, group, organization, community and population) levels
2. Design a qualitative, quantitative, mixed methods, policy analysis or evaluation project to address a public health issue
3. Explain the use and limitations of surveillance systems and national surveys in assessing, monitoring and evaluating policies and programs and to address a population’s health

Leadership, Management & Governance
4. Propose strategies for health improvement and elimination of health inequities by organizing stakeholders, including researchers, practitioners, community leaders and other partners
5. Communicate public health science to diverse stakeholders, including individuals at all levels of health literacy, for purposes of influencing behavior and policies
6. Integrate knowledge, approaches, methods, values and potential contributions from multiple professions and systems in addressing public health problems
7. Create a strategic plan
8. Facilitate shared decision making through negotiation and consensus-building methods
9. Create organizational change strategies
10. Propose strategies to promote inclusion and equity within public health programs, policies and systems
11. Assess one’s own strengths and weaknesses in leadership capacities including cultural proficiency
12. Propose human, fiscal and other resources to achieve a strategic goal
13. Cultivate new resources and revenue streams to achieve a strategic goal

**Policy & Programs**
14. Design a system-level intervention to address a public health issue
15. Integrate knowledge of cultural values and practices in the design of public health policies and programs
16. Integrate scientific information, legal and regulatory approaches, ethical frameworks and varied stakeholder interests in policy development and analysis
17. Propose interprofessional team approaches to improving public health

**Education & Workforce Development**
18. Assess an audience’s knowledge and learning needs
19. Deliver training or educational experiences that promote learning in academic, organizational or community settings
20. Use best practice modalities in pedagogical practices

**Student Learning Outcomes:**
Students will:
1. Express understanding of cross-sectional, case-control and cohort study designs (prospective and retrospective)
2. Demonstrate knowledge regarding exposure and outcome assessment in cross-sectional, case-control and cohort studies
3. Assess risk and impact of bias in cross-sectional, case-control and cohort studies
4. Demonstrate knowledge of methodological issues in cross-sectional, case-control and cohort studies
5. Understand techniques to minimize bias in cross-sectional, case-control and cohort studies
6. Understand strengths and limitations of cross-sectional, case-control and cohort studies
7. Critically evaluate observational study designs

**Assessment of Student Learning**

Homework assignments are designed to allow the student to demonstrate their understanding of the key concepts presented in class. Instructions for each homework assignment will be posted on Folio.

*Students may vary in their ability to achieve levels of competence in this course. Students can expect to achieve course competence only if they honor all course policies, attend classes regularly, complete all assigned work in good faith and on time, and meet all other course expectations of them as students.*
## Overview of the content to be covered the semester:

<table>
<thead>
<tr>
<th>Unit</th>
<th>Topic</th>
<th>Deliverable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Overview &amp; Introduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Designing Observational Studies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recruitment and Retention</td>
<td>Topics due 8/19 11:30pm</td>
</tr>
<tr>
<td>2</td>
<td>Discuss topic proposals</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sample Size &amp; Power Calculations</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cohort Studies I</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Cohort Studies II</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Cohort Studies III</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Case-Control Studies I</td>
<td>Assignment 1 Due: Cohort Study Design</td>
</tr>
<tr>
<td>7</td>
<td>Case-Control Studies II</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Case-Control Studies III</td>
<td>Midterm Exam</td>
</tr>
<tr>
<td>9</td>
<td>Case-Control Studies IV</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Cross-Sectional Studies I</td>
<td>Assignment 2 Due: Case-Control Study Design</td>
</tr>
<tr>
<td>11</td>
<td>Cross-Sectional Studies II</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Additional Topics in Observational Studies</td>
<td>Assignment 3 Due: Cross-Sectional Study Design</td>
</tr>
<tr>
<td>13</td>
<td>Ethical Issues in Observation</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Observational Studies vs. Randomized Controlled Trials</td>
<td>Assignment 4 Due: Observational Studies vs. RCTs</td>
</tr>
<tr>
<td>15</td>
<td>Thanksgiving Break</td>
<td></td>
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<tr>
<td>16</td>
<td>TBD</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Final Exam (tentative)</td>
<td></td>
</tr>
</tbody>
</table>

### Response times:

During a normal work week (i.e., Monday 9:00 AM through Friday 5:00 PM) students can expect responses as follows:

- Email: within 48 hours
- Discussion posts: within 72 hours
- Assignment grades: within 72 hours of submission date.

Exceptions: I do not check FOLIO or GSU email over the weekends. If you send me an email after 5:00 PM on Friday, please do not expect a response until the following Monday.

### Course Structure

This course will consist of lectures and discussion. The course is fast-paced and will require students to read prior to class each week, complete homework assignments, and contribute to
class discussions. Students should keep up with all assignments and should not allow themselves to fall behind since it will be very difficult to catch-up.

Assignments/Evaluations

The following assignments will be used to evaluate the performance of students in the course. The requirements for each assignment will be posted on Folio or handed-out in class. Students who are absent for a class period in which an assignment was given are responsible for obtaining the assignment from a classmate, Folio, or the instructor(s). There will be no opportunity for "extra credit" in this course. Grades will not be "curved". There will be no opportunity for "extra credit" in this course. The specific grading events for this course are as follows:

See Course Outline for specific topics and dates.

<table>
<thead>
<tr>
<th>Assignment</th>
<th>% of Final Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Not Graded</td>
</tr>
<tr>
<td>Cohort Study Design</td>
<td>10</td>
</tr>
<tr>
<td>Midterm exam</td>
<td>30</td>
</tr>
<tr>
<td>Case-control study design</td>
<td>10</td>
</tr>
<tr>
<td>Cross-sectional study design</td>
<td>10</td>
</tr>
<tr>
<td>Observational studies vs. clinical trials</td>
<td>10</td>
</tr>
<tr>
<td>Final Exam</td>
<td>30</td>
</tr>
</tbody>
</table>

Scoring
90+%=A,
80-89%=B,
70-79%=C,
60-69%=D,
Below 60%=F

1. ASSIGNED READINGS
Assigned readings should be done before class to enhance students' learning. The readings are important for completion of course assignments and class discussion.

2. HOMEWORK ASSIGNMENTS
Homework assignments are designed to allow the student to demonstrate their understanding of the key concepts presented in class. Instructions for each homework assignment will be posted on Folio.

Although many assignments will not be given an individual grade, each assignment is due on the date specified. The Instructor will only make comments and provide feedback on assignments submitted on time. Therefore, it is beneficial to you to turn in all assignments on time. Students are not permitted to work in groups on homework assignments unless it is specifically stated in the instructions of the assignment. Each assignment is an individual assignment and students are
expected to turn in their own original work. Plagiarism is a serious offense. If the course instructors feel that academic dishonesty may have occurred related to ANY grading event, the instructors will/may conduct an additional oral examination or other method of evaluation for the material covered. If plagiarized material is detected or it is found that the student has cheated on an assignment, the student may FAIL the course.

Assignment Due Dates: Assignments are expected to be turned in by being uploaded into Folio not later than the due date/time posted on the Folio dropbox/quiz.

Late submission of assignments will result in a grade reduction of 5% for every 24 hours, unless there is a documented personal or family emergency or illness. For example, for an assignment that is due on Thursday at 7:00 pm, if someone submits it on the coming Saturday at 6.59pm, then: Final Grade = Grade * 90%

There are times when extraordinary circumstances occur (e.g., serious illness, death in the family, etc.). In such circumstances, please consult with the instructor within a reasonable amount of time. The instructor will consult the college administrators and verify the reported circumstances before any exemptions or extensions can be granted. Extensions are not guaranteed and will be granted solely at the discretion of the instructor.

Following Directions: In order to receive full credit for each assignment, they must be turned in on time and all sections completed. Detailed instructions for completion of these exercises will be provided on Folio.

Failure to follow directions for the assignment (excessive spelling or grammatical errors, etc.) may result in the loss of 5 points from the final grade for each occurrence.

3. EXAMINATIONS
Examinations may include, but are not limited to, essay questions, multiple choice questions, matching and fill-in the blank. All exams will be held during the regular class session. Examinations will cover assigned readings and lecture material.

Course grading depends heavily on the student's ability to convey his or her thoughts in writing. Papers that are poorly written and/or have errors in spelling or grammar will not effectively convey the student's ideas. Thus, students who have difficulty with writing should seek help from a writing specialist and/or private tutor.

Academic Feedback:
Timely academic feedback will be provided as the course progresses. The professor intends to have components of the cumulative class grade reported to the student prior to the midpoint of the total grading period.

Prior to midpoint of the total grading period, all assigned and "turned in" graded class assignments and examinations should be graded and available to the student.
The student should make every effort to be available during the instructor's office hours for discussion of the student's academic standing prior to the midpoint of the total grading period (particularly for components that rely on subjective grading).

**Expectations:**

1. This is a 3-credit hour class. One credit is generally defined as the equivalent of roughly 3 hours of learning effort outside the classroom each week. Thus, for a course like this that meets 3 hours/week, you should expect approximately 6 hours of weekly coursework beyond the classroom. Since there are 15 classes (excluding Thanksgiving Break), you should expect approximately 90 hours of work outside of class this semester.

2. Students are expected to keep up with the class, to read the required material, and to submit assignments and activities by due dates and times.

3. Students are expected to independently complete all activities, exercises, assignments, and the final exam.

4. This course is fast-paced and students should not allow themselves to fall behind since it will be very difficult to catch-up. Students are also encouraged to contact the Instructor through email or Folio, if questions arise regarding presented material or course format.

5. To receive maximum points for any assignment, activity, exercises, or quiz questions, students need to follow the instructions carefully, follow word limits as instructed and use Spell Check. There will be deductions if these guidelines are not followed.

6. Remember to check when assignments are due. It is recommended that you stay ahead of schedule on the assignments, so if an emergency happens, your assignment will be completed and ready to submit within the designated time frame. It is your responsibility to keep track of the due dates for each assignment.

All assignments will be graded promptly so that students may accurately calculate their grades at any point in time during the semester. There are times when extraordinary circumstances occur (e.g., serious illness, death in the family, etc.). In such circumstances, and/or if you need additional time to satisfactorily complete any course requirement, please consult with the instructor within a reasonable amount of time.

There are times when extraordinary circumstances occur (e.g., serious illness, death in the family, etc.). In such circumstances, please consult with the instructor within a reasonable amount of time. Extensions are not guaranteed and will be granted solely at the discretion of the instructor.

**Class Attendance and Participation Policy**

Federal regulations require attendance be verified prior to distribution of financial aid allotments. Regular attendance is expected. Your attendance will be verified at the first regular class session.
It is the policy of the University to permit students, faculty, and staff to observe those holidays set aside by their chosen religious faith. The faculty should be sensitive to the observance of these holidays so that students who choose to observe these holidays are not seriously disadvantaged. It is the responsibility of those who wish to be absent to make arrangements in advance with their instructors.

Students participating in authorized activities as an official representative of the University (i.e., athletic events, delegate to regional or national meetings or conferences, participation in university-sponsored performances, and JPHCOPH funded) will not receive academic penalties and, in consultation with the instructor of record, will be given reasonable opportunities to complete assignments and exams or given compensatory assignment(s) if needed. The student must provide written confirmation from a faculty or staff advisor to the course instructor(s) at least 10 days prior to the date for which the student will be absent from the class. The student is responsible for all material presented in class and for all announcements and assignments. When possible, students are expected to complete these assignments before their absences. In the event of a disagreement regarding this policy, an appeal may be made by either the student or the instructor of record to the corresponding college dean. (University Graduate Catalog)

**Academic Misconduct**

As a student registered at this University, it is expected that you will adhere to only the strictest standards of conduct. It is recommended that you review the latest edition of the Student Conduct Code book, as well as the latest Undergraduate & Graduate Catalog to familiarize yourself with the University’s policies in this regard. Your continued enrollment in this course is an implied contract between you and the instructor on this issue; from this point forward, it is assumed that you will conduct yourself appropriately.

**Plagiarism:**

According to the Academic Dishonesty Policy of Georgia Southern University, Plagiarism includes (but is not limited to):

A. Directly quoting the words of others without using quotation marks or indented format to identify them.

B. Using published or unpublished sources of information without identifying them.

C. Paraphrasing material or ideas without identifying the source.

D. Unacknowledged use of materials prepared by another person or agency engaged in the selling of term papers or other academic material.

If you are accused of plagiarism by a JPHCOPH, the following policy, as per the Judicial Affairs website: (http://students.georgiasouthern.edu/judicial/faculty.htm) will be enforced:

**PROCEDURES FOR ADJUDICATING ACADEMIC DISHONESTY CASES**

**First Offense - In Violation Plea**

1. If the professor and the Dean of Students agree that the evidence is sufficient to warrant a charge of academic dishonesty, the professor should contact the Office of Judicial Affairs to
determine if this is a first violation of academic dishonesty. The incident will be reported via the following website:  http://students.georgiasouthern.edu/judicial/faculty.htm

2. If it is a first violation, the professor should talk with the student about the violation. **If the student accepts responsibility in writing and the professor decides to adjudicate the case, the following procedures will be followed:**
   a. The student will be placed on disciplinary probation for a minimum of one semester by the Office of Judicial Affairs.
   b. The student will be subject to any academic sanctions imposed by the professor (from receiving a 0 on the assignment to receiving a failing grade in the class).
   c. A copy of all the material involved in the case (Academic Dishonesty Report Form and the Request for Instructor to Adjudicate Form) and a brief statement from the professor concerning the facts of the case and the course syllabus should be mailed to the Office of Judicial Affairs for inclusion in the student’s discipline record.

**First Offense - Not in Violation Plea (student does not admit the violation)**

If the professor and the Dean of Students agree that the evidence is sufficient to warrant a charge of academic dishonesty, the professor should contact the Office of Judicial Affairs to determine if this is the first or second violation of academic dishonesty. The student will be charged with academic dishonesty and the University Judicial Board or a University Hearing Officer would hear the case. If the student is found responsible, the following penalty will normally be imposed:
   a. The student will be placed on Disciplinary Probation for a minimum of one semester by the Office of Judicial Affairs.
   b. The student will be subject to any academic sanctions imposed by the professor.

**Second Violation of Academic Dishonesty**

If the professor and the Dean of Students agree that the evidence is sufficient to warrant a charge of academic dishonesty, and if it is determined this is the second violation, the student will be charged with academic dishonesty and the University Judicial Board or a University Hearing Officer would hear the case. **If the student is found responsible, the following penalty will normally be imposed:**
   a. Suspension for a minimum of one semester or expulsion.
   b. The student will be subject to any academic sanctions imposed by the professor.

**NOT RESPONSIBLE FINDING**

When a student is found not responsible of academic dishonesty, the work in question (assignment, paper, test, etc.) would be forwarded to the Department Chair. It is the responsibility of the Chair to ensure that the work is evaluated by a faculty member other than the individual who brought the charge and, if necessary, submit a final grade to the Registrar. For the protection of the faculty member and the student, the work in question should not be referred back to the faculty member who charged the student with academic dishonesty. In the case of a Department Chair bringing charges against a student, an administrator at the Dean’s level will ensure that the student’s work is evaluated in an appropriate manner.

**CONFIDENTIALITY**

In accordance with provisions of the Family Educational Rights and Privacy Act of 1974 and the Georgia Open Records Act, any information related to a violation of academic dishonesty or the
outcome of a judicial hearing regarding academic dishonesty, is prohibited and must be treated as confidential by members of the faculty."

**Disability-related Accommodations**
Georgia Southern University is committed to providing reasonable accommodations to students with documented disabilities as required under federal law. Disabilities may include ADD or AD/HD, autism spectrum disorder, brain injury, chronic medical conditions, communication disorders, hearing loss, learning disabilities, mobility impairment, psychological disorders, visual impairment or temporary injuries. The purpose of disability accommodation is to provide equal access to the academic material and equal access to demonstrate mastery of the material. If you have a disability and need accommodations, please contact the Student Accessibility Resource Center (SARC). You will need to meet with a SARC staff member who can help you gather documentation of your disability or refer you to an appropriate resource for assessment. Once documentation of the disability is approved, SARC staff will provide you with an accommodation letter detailing the approved accommodations which you should present to me so we can discuss and implement your accommodations. Disability accommodations work best starting at the beginning of the semester, but can be approved and started at any point in the semester. Accommodations start at the time the accommodation letter is presented to faculty within reasonable timelines; accommodations are not given retroactively. SARC on the Statesboro campus is located on the second floor of Cone Hall and the phone number is (912) 478-1566. SARC for Savannah and Liberty campuses is located on the second floor of Memorial College Center and the phone number is (912) 344-2572.

**University Calendar for the Semester**
The University Calendar is located with the semester schedule, and can be found at: [http://em.georgiasouthern.edu/registrar/resources/calendars/](http://em.georgiasouthern.edu/registrar/resources/calendars/)

**Portfolio Inclusion**
Samples of your work may be reproduced for search purposes and/or inclusion in the professor’s teaching portfolio. You have the right to review anything selected for use, and subsequently ask for its removal.

**One Final Note**
The contents of this syllabus are as complete and accurate as possible. The instructor reserves the right to make any changes necessary to the syllabus and course material to ensure better student learning. The instructor will announce any such changes in class. It is the responsibility of the student to know what changes have been made in order to successfully complete the requirements of the course.

This syllabus, my lecture notes, and all materials distributed and presented during this course are protected by copyright law. You are authorized to take notes in this class but that authorization extends to only making one set of notes for your personal use and no other use. You are not authorized to sell, license, commercially publish, distribute, transmit, display, or record notes from this class unless you have my written consent to do so.
STUDENT CONDUCT CODE
The Student Conduct Code is the official University publication governing student conduct and behavior. It is the responsibility of each student to become familiar with the rules and regulations governing student life. Student conduct procedures, appeal procedures, and disciplinary sanctions are found in the Student Conduct Code at http://students.georgiasouthern.edu/conduct. I acknowledge that I have read and understand this statement referencing the Student Conduct Code.

ACADEMIC DISHONESTY
The University goal is to foster an intellectual atmosphere that produces educated, literate people. Because cheating and plagiarism are at odds with that goal, they shall not be tolerated in any form. Students are expected to adhere to the rules and regulations as set forth in the Student Conduct Code. Therefore, all work submitted by a student must represent that student's own ideas and effort; when the work does not, the student has engaged in academic dishonesty.
Plagiarism occurs when a person passes in another person's work as his or her own, borrows directly from another person's work without proper documentation, and resubmits his or her own work that has been previously submitted without explicit approval from the instructor. For example, academic dishonesty occurs whenever a student participates in any of the following: Cheating submitting material that is not yours as part of your course performance; using information or devices that are not allowed by the faculty; obtaining and/or using unauthorized materials; fabricating information, research, and/or results; violating procedures prescribed to protect the integrity of an assignment, test, or other evaluation; collaborating with others on assignments without the faculty's consent; cooperating with and/or helping another student to cheat; demonstrating any other forms of dishonest behavior. Plagiarism directly quoting the words of others without using quotation marks or indented format to identify them; using sources of information (published or unpublished) without identifying them; paraphrasing materials or ideas without identifying the source; self-plagiarism - resubmitting work previously submitted without explicit approval from the instructor; unacknowledged use of materials prepared by another person or agency engaged in the selling of term papers or other academic material.
NOTICE: The list above is intended only to provide general guidelines for recognizing and avoiding common types of academic dishonesty. It is in no way an exhaustive or comprehensive list of all the types of academic dishonesty. For more information about academic honesty, see the Student Conduct Code at http://students.georgiasouthern.edu/conduct. I acknowledge that I have read and understand the Academic Dishonesty Policy.

I have read the syllabus and understand the contents and course requirements.

________________________  _________________  __________________
Student Name (print)        Student Signature        Date