GMS 6812: Health Outcomes Research in Cancer
Department of Health Outcomes and Biomedical Informatics
College of Medicine
University of Florida

Semester: Fall 2019
Time: Fridays 9:35AM – 12:35PM
Location: HPNP G-110
Credits: 3
Instructor: Yi Guo, PhD; vigo@ufl.edu

COURSE DESCRIPTION
Understanding and measuring outcomes of health care has become increasingly important with a continued and growing focus on comparative effectiveness research, patient reported outcomes, quality of care and value-based purchasing for health care. This course is designed to focus on assessing cancer-related health outcomes. Outcomes research is broad and includes clinical endpoints such as toxic effects of drugs, clinical progression of disease and others. But it also includes functioning, health related quality of life (HRQOL), and patient reported outcomes.

AUDIENCE
The course is designed for advanced masters-level and doctoral-level students in health outcomes, biomedical informatics, medicine, public health, and other health professions, as well as advanced students in public policy, sociology, psychology or other social sciences with plans for a career in health research.

COURSE OBJECTIVES
The primary goals of this course are to enhance students’: (1) understanding for cancer outcomes; (2) ability to critically evaluate the measurement of cancer outcomes; and (3) experience in designing a protocol with an emphasis on the identification and analysis of cancer-related outcomes. More specifically, students who successfully complete the course will be able to:

1. Understand the terminologies and definition in cancer-related health outcome studies;
2. Demonstrate familiarity with the range of measures that are used to assess cancer health outcomes in the field of population sciences, comparative effectiveness research, patient reported outcomes, and cancer care cost analysis.
3. Compare and contrast measurement issues, methodological approaches, data sources, and statistical methods for assessing health outcomes for cancer patients; and
4. Critically evaluate specific cancer health outcomes assessment studies for their potential to inform clinical practice, cancer population science, and health care policy.

COURSE EVALUATION
Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu/results/.

**METHODS OF INSTRUCTION**

We will operate as an advanced graduate seminar, with students taking an active role in initiating and leading discussions and presenting their cancer outcomes measurement protocol progress. Attendance and active participation in all class discussions is required, and will be evaluated as part of the student’s grade for the course. Students must read the required readings prior to each class session.

**TESTS**

No exams will be given in this graduate-level seminar course.

**READING ASSIGNMENTS AND LEAD DISCUSSION**

The reading materials will be shared with you 2 weeks before discussion classes. You must read the assigned readings prior to class session and be prepared to discuss your reactions, thoughts, analysis, comments and questions on the main issues raised in the readings. Share what strikes you as new, unexpected, or particularly important. Discuss implications of that reading for your scientific work. Each student will be identified to lead one of the three discussion classes at the beginning of the semester. To lead the discussion, students are encouraged to use creative ways (e.g. PowerPoints, develop discussion questions, etc.) All students are expected to participate in each class discussion.

**TERM PAPER/PROTOCOL DEVELOPMENT (See additional information at the end of the syllabus)**

As described in the course introduction, students will develop a study protocol to assess cancer-related outcomes. The protocol can focus on any type of cancer outcomes (i.e. cancer incidence, prevalence, QoL, cost, etc.). The protocol will contain the following sections:

1) **Specific Aims** – What is the critical cancer prevention, clinical, palliative care or end-of-life care issue, the setting and the patient population? What evidence-based intervention for this issue will be the focus of your study? What are the key outcomes that will be measured to address the critical issue? Why have you selected these outcomes? What impact would this study have on improving patient outcomes (clinical, health related quality of life)? Costs? Clinician and patient satisfaction and engagement?

2) **Literature Review**
   a. Significance: Describe in more detail the issue and the evidence base selecting the issue. Describe in more detail why the outcomes you have chosen are critical. Select and describe an appropriate conceptual framework to guide your study aims and hypotheses, study design, choice of outcomes and interpretation of findings.
   b. Innovation: Explain how the application challenges and seeks to shift current research, prevention, clinical practice, and/or cancer-care paradigms
3) **Approach**
   a. Description of the study setting
   b. Description of the study population
   c. Study design
   d. Sample size considerations if applicable
   e. Specification of cancer outcomes – be specific here about how you are specifying each of the selected outcome variables and the rationale for selecting them, their reliability and validity, applicability to the topic
   f. Intervention approach or explanation of observational approach
   g. Data collection plan or data sources
   h. Data analysis plan – be specific about the statistical methods
   i. Strengths and limitations of the approach – be very specific here about how you will address potential barriers to collecting your outcomes of interest.
   j. Dissemination plans

4) **Human Subjects consideration**
   a. IRB protocol approval statement
   b. Inclusion of women, children, and minorities

5) **Data sharing plans**

6) **Data safety and monitoring plans**

**Protocol Presentation guidelines:**
You are expected to share the progress of your protocol at three presentations during the second half of the semester, with the 4th presentation showcasing your finalized protocol. For the first three presentations, you are welcomed to bring your drafted protocol to class for discussion in word or PowerPoint format. For the final presentation, you should prepare a well-designed set of slides in a PowerPoint file, which you will use during your presentations and will email to the entire class and the attendees (according to an attendee list that will be provided to you) at least 4 business days before the final presentation date. Design each visual carefully to illustrate the main points. Remember the rules for clear, easy to understand, and interesting slides: No more than 8 words per line, and no more than 8 lines on a slide; prevalent use of diagrams, charts, etc. to illustrate points; minimize the number of word-only slides; and aim for about one slide per minute.

**EVALUATION AND GRADING**
Grades will be based on class participation and lead class discussion (20%); Three protocol Progress Presentation (45%); Study Protocol (20%), Final Presentation (15%). All deadlines must be met. Any assignment turned in after the deadline will receive one grade below what it would have earned had it been submitted on time. Grades will be assigned as follows:

<table>
<thead>
<tr>
<th>Letter Grade</th>
<th>Grade Points</th>
<th>Grade Percentage</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>4.0</td>
<td>95-100</td>
</tr>
<tr>
<td>A-</td>
<td>3.67</td>
<td>90-94</td>
</tr>
<tr>
<td>B+</td>
<td>3.33</td>
<td>87-89</td>
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<tr>
<td>Grade</td>
<td>Value</td>
<td>Range</td>
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<td>-------</td>
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<tr>
<td>B</td>
<td>3.0</td>
<td>83-86</td>
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<tr>
<td>B-</td>
<td>2.67</td>
<td>80-82</td>
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<tr>
<td>C+</td>
<td>2.33</td>
<td>77-79</td>
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<tr>
<td>C</td>
<td>2.0</td>
<td>73-76</td>
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<tr>
<td>C-</td>
<td>1.67</td>
<td>70-72</td>
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<tr>
<td>D+</td>
<td>1.33</td>
<td>67-69</td>
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<tr>
<td>D</td>
<td>1.0</td>
<td>63-66</td>
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<tr>
<td>D-</td>
<td>0.67</td>
<td>60-62</td>
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<tr>
<td>E</td>
<td>0</td>
<td>59 and below</td>
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For additional grading policy information, you may visit the undergraduate catalog web page at [https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx](https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx).

**COURSE POLICIES**

Students are expected to adhere to the following course policies.

**Class Attendance**

Class attendance is required. Excused absences follow the criteria of the UF Graduate Catalog (e.g., illness, serious family emergency, military obligations, religious holidays), and should be communicated to the instructor prior to the missed class day when possible. University of Florida rules require attendance during the first two course sessions, and students must attend all course sessions of student presentations for this class. Missing more than three scheduled sessions will result in a failure. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments. Finally, students must read the assigned readings prior to the class meetings, and be prepared to discuss the material. For more information, please visit: [https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx](https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx)

**Class Decorum**

Please: (1) be on time, (2) respect others’ points of view, (3) listen quietly when others are speaking, and (4) turn off cell phones, alarms, and other such distractions.

**CANVAS**

Course information, readings, and grades are available on Canvas at [http://lss.at.ufl.edu/](http://lss.at.ufl.edu/). You must have a Gatorlink account to log on. You are expected to check the web site on a regular basis (i.e., at least one day prior to each class meeting).

**GETTING HELP**

For issues with technical difficulties for E-learning in Canvas, please contact the UF Help Desk at: learning-support@ufl.edu or by calling (352) 392-HELP - select option 2. Additional information is available at: [https://lss.at.ufl.edu/help.shtml](https://lss.at.ufl.edu/help.shtml)

**Returned Assignments**

Keep copies of all assignments that you submit and of all grades until you receive official notification of your final course grade.
Policy on Make-Up Work
Students are allowed to make up work only as the result of illness or other unanticipated circumstances. In the event of such emergency, documentation will be required in conformance with university policy. Work missed for any other reason will earn a grade of zero.

Accommodations for Students with Disabilities
Students requiring accommodations must first register with the Dean of Students' Office. The Dean of Students' Office will provide documentation to the student who must then provide this documentation to the faculty member when requesting accommodation. The College is committed to providing reasonable accommodations to assist students in their coursework.

COUNSELING & MENTAL HEALTH SERVICES
Please visit the UF counseling center website for information regarding appointments: https://counseling.ufl.edu/ or call (352)392-1575

UF POLICE DEPARTMENT
For Campus Police, please call the UF Police Department at 352)392-1111
For all emergencies and medical assistance, please call 911.

TEXTBOOK

Online Course Evaluations
Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu.

SCHEDULE OF TOPICS AND READINGS

<table>
<thead>
<tr>
<th>Date</th>
<th>Lectures</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/23/2019</td>
<td>Course overview</td>
</tr>
<tr>
<td>08/30/2019</td>
<td>Class Discussion 1: Cancer burden</td>
</tr>
<tr>
<td>09/06/2019</td>
<td>Guest Speaker: Cancer outcome in social media (09/06)</td>
</tr>
<tr>
<td>09/13/2019</td>
<td>Cancer burden- Lab</td>
</tr>
<tr>
<td>09/20/2019</td>
<td>Class Discussion 2: Patient reported outcomes and Quality of life</td>
</tr>
<tr>
<td>09/27/2019</td>
<td>Class Discussion 3: Cancer screening programs</td>
</tr>
<tr>
<td>10/04/2019</td>
<td>No class - Homecoming</td>
</tr>
<tr>
<td>10/11/2019</td>
<td>1st presentation for proposal- Research question and literature review</td>
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</tbody>
</table>
Class Discussion 1 - Magnitude of Cancer in the U.S. and General Concepts in Cancer Health Outcomes Assessment

Readings:


Class Discussion 2: Patient Reported Outcomes

Readings:

Class Discussion 3: Cancer Screening (TBD)

Resources for preparation of 7-page abbreviated proposals, Use ½ margins and Arial 11 font.

**Specific Aims**
State concisely the goals of the proposed research and summarize the expected outcome(s), 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. Be sure to list the very specific few research questions or hypotheses to be tested in the proposed study.

**Significance**
Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field.

**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.

**Approach**
Describe the research design, conceptual or clinical framework, outcomes selected (include their reliability and validity, applicability to your population and topic) procedures (include how you will collect the data, barriers to data collection and how you will overcome these barriers), and analyses. Describe any new methods and their advantage over existing methods. Describe any novel concepts, outcome measures, approaches, tools, or technologies for the proposed studies. Discuss how threats to validity are addressed by the design. Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

**Human Subjects consideration (no page limit)**
   a. IRB protocol approval statement
   b. Inclusion of women, children, and minorities

**Data Sharing and Dissemination Plans (1/2 page)**
Data Safety and Monitoring Plans (no page limit)

Literature cited (no page limit; does not count toward 6 pages)
  a. Use AMA or APA guidelines, be accurate and consistent

NIH R01 Instructions from website: