**Comparative Effectiveness Research (M19-5252)**

Spring 2019 (1/14/19 – 5/7/19)
Fridays, 1:00-3:00pm
Location: Taylor Avenue Building 2nd floor, Richmond Room

**INSTRUCTOR**

Erika A. Waters, PhD, MPH
Division of Public Health Sciences
Department of Surgery
waterse@wustl.edu
Phone: 314-747-5705
Office Hours: By appointment

**COURSE DESCRIPTION & OBJECTIVES**

This course will provide a comprehensive introduction to comparative effectiveness research (CER). Topics include an overview of CER, stakeholder engagement in CER, designing CER studies, methodologic challenges in doing CER, and recent developments in PCORI and Federal policy. Students will be expected to review and evaluate comparative effectiveness studies as well as actively participate in class discussions. Many class sessions will include a case study. Through examples, class discussion, and homework students will become familiar with CER methods. They will prepare a set of specific aims for a CER project and identify gaps in CER in their field of study.

**COMPETENCIES**

- Define CER and its basic tenets.
- Understand the broader context of CER
- Identify common methodologies used in CER
- Be able to identify the appropriate research design for the CER question
- Identify methodologic challenges of CER

**COURSE FORMAT & EXPECTATIONS**

This class is based on a diverse array of activities, including lectures, discussions, reading assignments, study critiques, and in-class case studies. Students must come to each session prepared to be active, thoughtful, and energetic participants. This requires thoughtful and careful reading of assigned course materials prior to each class session.

**STUDENT RESPONSIBILITIES**

- Attend each class.
- Come to class on-time, prepared, and having read all required readings.
- Participate in class discussions and complete in-class case studies.
- Complete assignments on time.
Seek any necessary clarification regarding course expectations.

Any issues with attendance, deadlines, or completion of assignments should be discussed before the deadline/class with the instructor. Email is the best way to contact the instructor. Emails will be answered within two business days with the exception of weekends and holidays.

CLASSROOM ETIQUETTE

- Please turn all cellphones and pagers to silent or vibrate.
- If you need to answer a call or page, please leave the room quietly to do so.
- Do not use the internet for non-class purposes, social media sites, BJC clinical sites, or check email during class time.
- Please be respectful of differences in viewpoints expressed during class discussion.
- Please keep any sensitive information that arises during discussion confidential.

CANVAS

We will use Canvas to manage our class, access assignment instructions and post course-related questions. Canvas can be accessed at https://mycanvas.wustl.edu/. Log in to the Wash U MyCanvas version (NOT the MD program version) with your WUSTLKey and the class should appear on the homepage.

- All updates and reminders will be posted on Canvas.
- Lecture notes and additional readings and assignment instructions will be posted on Canvas throughout the semester.

We may utilize the Discussion threads for general questions related to lectures and assignments. Students should post all general questions that may be relevant to others in class to the Discussion thread. Student-specific questions (e.g. related to a grade or exam conflict) should be emailed directly to the instructors. Every effort will be made to answer student emails within 48-hours (excluding weekends). Students are encouraged to post materials related to class (e.g. link to a news story) on Canvas for the rest of the class to access.

EVALUATION AND GRADING

Grades will be based on class participation and assignments. Additional specific details for each assignment will be distributed at least 4 week prior to their due date.

1. Class participation (15 points): The participation portion of the course grade is based upon regular and timely attendance, as well as active, meaningful contributions to class discussion and case studies. Students are expected to read the required readings. Participation points are earned by arriving to class on time and being an active and thoughtful contributor to class discussions. More than two absences from class may result in a lowered grade. Please consider not enrolling if you have more than two absences already planned.

2. Journal article critique and presentation (25 points): You will be required to give a 25 min journal club-style review of an article of your choice in class. The only requirement is that it be an original research article and that it be related to CER. The full citation for your selected reading must be emailed to the entire class no later than 12pm the Monday before the day you are scheduled. This allows time for the instructor to review materials and to get readings to your classmates in a timely manner. Detailed instructions to follow.
3. **Project outline (10 points):** A one page Project Outline to describe key aspects of your planned CER project. Please use the provided Project Outline template on Canvas, and submit your completed outline on Canvas. **The project outline is due March 15, 2019 at 11:59pm.**

4. **Letter of Intent (30 points):** Students will be asked to submit a modified PCORI Letter of Intent (LOI) 3 page limit excluding references) describing a CER study. The proposed study may be of any type of study design, as long as it meets the criteria for a CER study, as discussed in class and in the LOI instructions. Please submit your completed LOI on Canvas. **The LOI is due April 19, 2019 at 11:59pm.**

5. **Project presentation (20 points):** Students will give a 15-minute PowerPoint presentation describing the CER project they proposed in the LOI. **The presentations will be held either April 26 or May 3, 2019.**

**Grading**

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<thead>
<tr>
<th>Component</th>
<th>Points</th>
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<tr>
<td>Participation</td>
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<td>Article critique</td>
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<td>Project outline</td>
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**Grading scale:**

- **A:** 90-100 points
- **B:** 80-89 points
- **C:** 70-79 points
- **F:** less than 69 points

**Late assignments:** Late assignments will result in a deduction of five points for each day late **including weekends** unless prior approval is obtained from the instructor or a compelling situation prevents prior approval (i.e. documented health issues or family emergencies).

**ACADEMIC HONESTY**

Students are expected to complete all of their assignments in accordance with Washington University in St. Louis’ academic rules and regulations regarding honesty and integrity. Any evidence of academic misconduct, including cheating, failure to cite sources, and/or plagiarism will result in appropriate action as dictated by Washington University in St. Louis. Violations of academic honesty will result in notification to the Associate Dean of Academic Affairs at the Washington University School of Medicine, as well as the MPHS Director, Assistant Director(s), and Program Committee. Any hint of violation during an examination or in a written assignment will result in no grade for the exam/assignment. For more information see the University's Student Academic Integrity Policy.

**SPECIAL NEEDS**

Per University policy, students with learning, sensory, or physical disability or other impairment should contact the Washington University Center for Advanced Learning Disability Resources (DR) at 314-935-4062 or visit [http://disability.wustl.edu/DisabilityResources.aspx](http://disability.wustl.edu/DisabilityResources.aspx). The DR Office is located in Cornerstone on the Danforth Campus.

Students whose second language is English and/or those in need of assistance in lectures, reading or writing assignments, and/or testing, should contact the University Writing Center at 314-935-4981 or visit [https://writingcenter.wustl.edu/](https://writingcenter.wustl.edu/).
COURSE SCHEDULE

**The syllabus is subject to change at the discretion of the instructor.**

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<th>Session</th>
<th>Date</th>
<th>Topic</th>
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<tr>
<td>1</td>
<td>Jan 18</td>
<td>Overview of the Course and CER</td>
<td>Erika Waters</td>
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<td>2</td>
<td>Jan 25</td>
<td>Large Databases for Retrospective CER Studies</td>
<td>Anne Mobley Butler</td>
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<td>3</td>
<td>Feb 1</td>
<td>Consumer Engagement in CER Studies</td>
<td>Mary Politi</td>
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<td>4</td>
<td>Feb 8</td>
<td>Effectiveness and Pragmatic Trials</td>
<td>Shane LaRue</td>
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<td>5</td>
<td>Feb 15</td>
<td>Case Study: Pragmatic Trial</td>
<td>Kaharu Sumino</td>
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<td>6</td>
<td>Feb 22</td>
<td>CER Systematic Reviews &amp; Meta Analyses</td>
<td>Su-Hsin Chang</td>
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<td>7</td>
<td>Mar 1</td>
<td>Cost Effectiveness CER Studies</td>
<td>Su-Hsin Chang</td>
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<td>8</td>
<td>Mar 8</td>
<td>Prospective Observational CER Studies</td>
<td>Siobhan Sutcliffe</td>
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<td>9</td>
<td>Mar 15</td>
<td>Case Study: Large Database and Cost Effectiveness Research</td>
<td>Varun Puri</td>
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<td>Mar 22</td>
<td>Case Study: Stakeholder Engagement from the Researcher Perspective</td>
<td>Vetta Thompson</td>
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<td>11</td>
<td>Mar 29</td>
<td>Patient-Reported Outcome Measures</td>
<td>Amy McQueen</td>
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<td>12</td>
<td>Apr 5</td>
<td>Implementation CER Studies</td>
<td>Stephanie Mazzucca</td>
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<td>13</td>
<td>Apr 12</td>
<td>Case Study: Stakeholder Engagement from the Stakeholder Perspective</td>
<td>Elizabeth Kruvand</td>
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<td>14</td>
<td>Apr 19</td>
<td>Case Study: Patient Centered Outcomes in Anesthesia</td>
<td>Michael Avidan</td>
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<td>15</td>
<td>Apr 26</td>
<td>Student presentations</td>
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<td>16</td>
<td>May 3</td>
<td>Student presentations</td>
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READINGS AND RESOURCES

A schedule of required and recommended readings will be provided. Additional readings related to student presentations will be distributed a few days before each class. Below are some general resources related to our topic:

**Class Background Material:**


- IOM initial priorities for CER [https://www.nap.edu/read/12648/chapter/1](https://www.nap.edu/read/12648/chapter/1)


**January 18 (Session 1): Overview of the Course and CER (Waters)**

1. Sox HC. Defining comparative effectiveness research: the importance of getting it right. Med Care 2010;48(6


5. PCORI methodology standards (latest update 2018): [https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards](https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards) or [https://www.pcori.org/sites/default/files/PCORI-Methodology-Standards.pdf](https://www.pcori.org/sites/default/files/PCORI-Methodology-Standards.pdf) Although the standards are written as though they are specific to PCORI, they represent generally good research practices overall and therefore can be applied to proposals for multiple funding agencies and for various types of research projects.

January 25 (Session 2): Overview of Large Databases for Retrospective CER Studies (Butler)


February 1 (Session 3): Consumer Engagement in CER Trials (Politi)


4. PCORI resources: Although these are written to be specific to PCORI, the basic principles (e.g., a written
engagement plan) can be applied to other research projects and funding opportunities.

a. [http://www.pcori.org/funding-opportunities/what-we-mean-engagement](http://www.pcori.org/funding-opportunities/what-we-mean-engagement)

**February 8 (Session 4): Effectiveness and Pragmatic Trials (LaRue)**


**February 15 (Session 5): Case Study – Pragmatic Trials (Sumino)**


2. This article is not precisely CER because it doesn’t compare two treatments with demonstrated effectiveness, but it includes a variety of design features that may be of interest. It is also relevant to the cost effectiveness session. Smith JR, Musgrave S, Payerne E, et al. At-risk registers integrated into primary care to stop asthma crises in the UK (ARRISA-UK): study protocol for a pragmatic, cluster randomised trial with nested health economic and process evaluations. Trials. 2018;19(1):466. Published 2018 Aug 29. doi:10.1186/s13063-018-2816-z


**February 22 (Session 6): CER Systematic Reviews & Meta Analyses (Chang)**


4. AHRQ Methods guide for Effectiveness and Comparative Effectiveness Reviews:  
   http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&mp=1&productID=318

5. AHRQ also has a slide library for training for systematic reviews with their focus on comparative effectiveness:  
   http://www.effectivehealthcare.ahrq.gov/index.cfm/tools-and-resources/slide-library/#slidetrainingmodules

**March 1 (Session 7): Cost Effectiveness CER Studies (Chang)**


3. Review the relevant portions of the Smith et al., Trials, 2018 article from class session 5.


**March 8 (Session 8): Prospective Observational CER Studies (Sutcliffe)**


**March 15 (Session 9): Case Study – Large Database and Cost Effectiveness (Puri)**


March 22 (Session 10): Case Study – Stakeholder Engagement from the Researcher Perspective (Sanders Thompson)


March 29 (Session 11): Patient-Reported Outcome Measures (McQueen)


April 5 (Session 12): Implementation CER Studies (Mazzucca)


**April 12 (Session 13): Case Study – Stakeholder Engagement from the Stakeholder Perspective (Kruvand)**


**April 19 (Session 14): Case Study – Patient Centered Outcomes in Anesthesia (PROMIS) (Avidan)**

No readings for this class session.

**April 26 (Session 15): Student Presentations**

**May 3 (Session 16): Student Presentations**